Systematic Literature Review: Drug Eluting Intracoronary Stents

Database:	PubMed
Search string:	stent$ AND (coronary OR cardiac OR heart) AND (DES OR drug eluting stent$) NOT (BMS OR bare metal stent$)
Limits:	Metaanalysis or RCT, humans, English language, abstract available, published in last 5 years
Citations:	149

Inclusion criteria

- Randomized controlled trials (RCTs) or meta-analysis of RCTs comparing different types of DES stents as to associated clinical outcomes, or angiographic and/or intravascular ultrasound outcomes concerning in-stent late loss, percentage volume obstruction or other measures of intrastent luminal stenosis.

Exclusion criteria

- Studies comparing PCI using DES stents to PCI using Bare Metal Stents, CABG or medical treatment.
- Studies assessing the safety and effectiveness of anti-platelet therapy administered after the implantation of DES stents.
- Studies assessing clinical outcomes associated with the use of therapies/procedures adjunctive to DES stent implantation, such as the use of vascular filters, antiplatelet therapy, intracoronary adenosine administration, etc.
- Studies evaluating the association between independent variables (such as BMI, genetic polymorphisms, target vessel size, presense or not of diabetes, etc) and the clinical outcomes of DES stent implantation.
- Studies comparing different stenting techniques for bifurcated lesions, as to their clinical and/or radiologic outcomes.
- Articles describing trial design without providing clinical trial results.
- Studies assessing edge effects of different DES stents.
- Studies assessing the clinical and/or economic effectiveness of using FFR to guide stenting decisions.
- Studies assessing the effect of DES stenting on biochemical or physiological mechanisms.
- Pharmacokinetic studies of stent-eluted drugs.

44 μελέτες επιλέχτηκαν με βάση τα παραπάνω κριτήρια.

Επιλεχθέντες μελέτες (44):

1. N Engl J Med. 2010 May 6;362(18):1663-74.

Everolimus-eluting versus paclitaxel-eluting stents in coronary artery disease.

Stone GW, Rizvi A, Newman W, Mastali K, Wang JC, Caputo R, Doostzadeh J, Cao S, Simonton CA, Sudhir K, Lansky AJ, Cutlip DE, Kereiakes DJ; SPIRIT IV Investigators.

Columbia University Medical Center/New York-Presbyterian Hospital and the Cardiovascular Research Foundation, New York, NY 10022, USA. gs2184@columbia.edu

Comment in:

- N Engl J Med. 2010 May 6;362(18):1728-30.

Abstract

BACKGROUND: Previous studies have established the superiority of coronary everolimus-eluting stents over paclitaxel-eluting stents with respect to angiographic findings. However, these trials were not powered for superiority in clinical end points. METHODS: We randomly assigned 3687 patients at 66 U.S. sites to receive everolimus-eluting stents or paclitaxel-eluting stents without routine follow-up angiography. The primary end point was the 1-year composite rate of target-lesion failure (defined as cardiac death, target-vessel myocardial infarction, or ischemia-driven target-lesion revascularization). RESULTS: Everolimus-eluting stents were superior to paclitaxel-eluting stents with respect to the primary end point of target-lesion failure (4.2% vs. 6.8%; relative risk, 0.62; 95% confidence interval, 0.46 to 0.82; P=0.001). Everolimus-eluting stents were also superior with respect to the major secondary end point of the 1-year rate of ischemia-driven target-lesion revascularization (P=0.001) and were noninferior with respect to the major secondary end point of the 1-year composite rate of cardiac death or target-vessel myocardial infarction (P<0.001 for noninferiority; P=0.09 for superiority). The 1-year rates of myocardial infarction and stent thrombosis were also lower with everolimus-eluting stents than with paclitaxel-eluting stents (1.9% vs. 3.1%, P=0.02 for myocardial infarction; 0.17% vs. 0.85%,

P=0.004 for stent thrombosis). Target-lesion failure was consistently reduced with everolimus-eluting stents as compared with paclitaxel-eluting stents in 12 prespecified subgroups, except in the subgroup of patients with diabetes (6.4% vs. 6.9%, P=0.80). CONCLUSIONS: Everolimus-eluting stents, as compared with paclitaxel-eluting stents, resulted in reduced rates of target-lesion failure at 1 year, results that were consistent in all patients except those with diabetes, in whom the results were nonsignificantly different. (ClinicalTrials.gov number, NCT00307047.) 2010 Massachusetts Medical Society

 2.

Lancet. 2010 Mar 27;375(9720):1090-9. Epub 2010 Mar 16.

Efficacy and safety of zotarolimus-eluting and sirolimus-eluting coronary stents in routine clinical care (SORT OUT III): a randomised controlled superiority trial.

Rasmussen K, Maeng M, Kaltoft A, Thayssen P, Kelbaek H, Tilsted HH, Abildgaard U, Christiansen EH, Engstrøm T, Krusell LR, Ravkilde J, Hansen PR, Hansen KN, Abildstrøm SZ, Aarøe J, Jensen JS, Kristensen SD, Bøtker HE, Madsen M, Johnsen SP, Jensen LO, Sørensen HT, Thuesen L, Lassen JF; SORT OUT III study group.

Collaborators (13)
Rasmussen K, Thygesen K, Nørgaard BL, Terkelsen CJ, Madsen M, Johnsen SP, Sørensen HT, Rasmussen K, Tilsted HH, Thayssen P, Kelbaek H, Lassen JF, Thuesen L.

Department of Cardiology, Aarhus University Hospital, Aalborg Hospital, Aalborg, Denmark.

Comment in:

- Lancet. 2010 Mar 27;375(9720):1060-2.
- Nat Rev Cardiol. 2010 May;7(5):240.

Abstract

BACKGROUND: In low-risk patients, the zotarolimus-eluting stent has been shown to reduce rates of restenosis without increasing the risk of stent thrombosis. We compared the efficacy and safety of the zotarolimus-eluting stent versus the sirolimus-eluting stent in patients with coronary artery disease who were receiving routine clinical care with no direct follow-up. METHODS: We did a single-blind, all-comer

superiority trial in adult patients with chronic stable coronary artery disease or acute coronary syndromes, and at least one target lesion. Patients were treated at one of five percutaneous coronary intervention centres between January, 2006, and August, 2007. Computer-generated block randomisation and a telephone allocation service were used to randomly assign patients to receive the zotarolimus-eluting or the sirolimus-eluting stent. Data for follow-up were obtained from national Danish administrative and health-care registries. The primary endpoint was a composite of major adverse cardiac events within 9 months: cardiac death, myocardial infarction, and target vessel revascularisation. Intention-to-treat analyses were done at 9-month and 18-month follow-up. This trial is registered with ClinicalTrials.gov, number NCT00660478. FINDINGS: 1162 patients (1619 lesions) were assigned to receive the zotarolimus-eluting stent, and 1170 patients (1611 lesions) to receive the sirolimus-eluting stent. 67 patients (72 lesions) had stent failure, and six patients were lost to follow-up. All randomly assigned patients were included in analyses at 9-month follow-up; 2200 patients (94%) had completed 18-month follow-up by the time of our assessment. At 9 months, the primary endpoint had occurred in a higher proportion of patients treated with the zotarolimus-eluting stent than in those treated with the sirolimus-eluting stent (72 [6%] vs 34 [3%]; HR 2.15, 95% CI 1.43-3.23; p=0.0002). At 18-month follow-up, this difference was sustained (113 [10%] vs 53 [5%]; 2.19, 1.58-3.04; p<0.0001). For patients receiving the zotarolimus-eluting stent and those receiving the sirolimus-eluting stent, all cause-mortality was similar at 9-month follow-up (25 [2%] vs 18 [2%]; 1.40, 0.76-2.56; p=0.28), but was significantly different at 18-month follow-up (51 [4%] vs 32 [3%]; 1.61, 1.03-2.50; p=0.035). INTERPRETATION: The sirolimus-eluting stent is superior to the zotarolimus-eluting stent for patients receiving routine clinical care. FUNDING: Cordis and Medtronic.

PMID: 20231034 [PubMed - indexed for MEDLINE]

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3.

J Am Coll Cardiol. 2010 Feb 9;55(6):543-54.

A randomized comparison of the ENDEAVOR zotarolimus-eluting stent versus the TAXUS paclitaxel-eluting stent in de novo native coronary lesions 12-month outcomes from the ENDEAVOR IV trial.

Leon MB, Mauri L, Popma JJ, Cutlip DE, Nikolsky E, O'Shaughnessy C, Overlie PA, McLaurin BT, Solomon SL, Douglas JS Jr, Ball MW, Caputo RP, Jain A, Tolleson TR, Reen BM 3rd, Kirtane AJ, Fitzgerald PJ, Thompson K, Kandzari DE; ENDEAVOR IV Investigators.

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Comment in:

- J Am Coll Cardiol. 2010 Feb 9;55(6):555-7.

Abstract

OBJECTIVES: The ENDEAVOR IV (Randomized Comparison of Zotarolimus-Eluting and Paclitaxel-Eluting Stents in Patients with Coronary Artery Disease) trial evaluated the safety and efficacy of the zotarolimus-eluting stent (ZES) compared with the paclitaxel-eluting stent (PES). BACKGROUND: First-generation drug-eluting stents have reduced angiographic and clinical restenosis, but long-term safety remains controversial. A second-generation drug-eluting stent, which delivers zotarolimus, a potent antiproliferative agent, via a biocompatible phosphorylcholine polymer on a cobalt alloy thin-strut stent has shown promising experimental and early clinical results. METHODS: This is a prospective, randomized (1:1), single-blind, controlled trial comparing outcomes of patients with single de novo coronary lesions treated with ZES or PES. The primary end point was noninferiority of 9-month target vessel failure defined as cardiac death, myocardial infarction, or target vessel revascularization. RESULTS: Among a total of 1,548 patients assigned to ZES (n = 773) or PES (n = 775), at 9 months, ZES was noninferior to PES (Myrsini's note: this seems to concern the 9-mo results)with rates of target vessel failure 6.6% versus 7.1%, respectively (p(noninferiority) < or = 0.001). There were fewer periprocedural myocardial infarctions with ZES (0.5% vs. 2.2%; p = 0.007), whereas at 12 months, there were no significant differences between groups in rates of cardiac death, myocardial infarction, target vessel revascularization, or stent thrombosis. Although incidence of 8-month binary angiographic in-segment restenosis was higher in patients treated with ZES versus PES (15.3% vs. 10.4%; p = 0.284), rates of 12-month target lesion revascularization were similar (4.5% vs. 3.2%; p = 0.228), especially in patients without planned angiographic follow-up (3.6% vs. 3.2%; p = 0.756). CONCLUSIONS: These findings demonstrate that ZES has similar clinical safety and efficacy compared with PES in simple and medium complexity single de novo coronary lesions. (ENDEAVOR IV Clinical Trial; NCT00217269).

PMID: 20152559 [PubMed - indexed for MEDLINE]

4.

JACC Cardiovasc Interv. 2009 Dec;2(12):1208-18.

Late safety, efficacy, and cost-effectiveness of a zotarolimus-eluting stent compared with a paclitaxel-eluting stent in patients with de novo coronary lesions: 2-year follow-up from the ENDEAVOR IV trial (Randomized, Controlled Trial of the Medtronic Endeavor Drug [ABT-578] Eluting Coronary Stent System Versus the Taxus Paclitaxel-Eluting Coronary Stent System in De Novo Native Coronary Artery Lesions).

Leon MB, Kandzari DE, Eisenstein EL, Anstrom KJ, Mauri L, Cutlip DE, Nikolsky E, O'Shaughnessy C, Overlie PA, Kirtane AJ, McLaurin BT, Solomon SL, Douglas JS Jr, Popma JJ; ENDEAVOR IV Investigators.

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Comment in:

- JACC Cardiovasc Interv. 2009 Dec;2(12):1236-9.

Abstract

OBJECTIVES: The aim of this study was to assess, after 2 years of follow-up, the safety, efficacy, and cost-effectiveness of a zotarolimus-eluting stent (ZES) compared with a paclitaxel-eluting stent (PES) in patients with native coronary lesions. BACKGROUND: Early drug-eluting stents were associated with a small but significant incidence of very late stent thrombosis (VLST), occurring >1 year after the index procedure. The ZES has shown encouraging results in clinical trials. METHODS: The ENDEAVOR IV trial (Randomized, Controlled Trial of the Medtronic Endeavor Drug [ABT-578] Eluting Coronary Stent System Versus the Taxus Paclitaxel-Eluting Coronary Stent System in De Novo Native Coronary Artery Lesions), a randomized (1:1), single-blind, controlled trial (n = 1,548) compared ZES versus PES in

patients with single de novo coronary lesions. Two-year follow-up was obtained in 96.0% of ZES and 95.4% of PES patients. The primary end point was target vessel failure (TVF), and safety end points included Academic Research Consortium-defined stent thrombosis. Economic end points analyzed included quality-adjusted survival, medical costs, and relative cost-effectiveness of ZES and PES. RESULTS: The TVF at 2 years was similar in ZES and PES patients (11.1% vs. 13.1%, p = 0.232). There were fewer myocardial infarctions (MIs) in ZES patients (p = 0.022), due to fewer periprocedural non-Q-wave MIs and fewer late MIs between 1 and 2 years. Late MIs were associated with increased VLST (PES: 6 vs. ZES: 1; p = 0.069). Target lesion revascularization was similar comparing ZES with PES (5.9% vs. 4.6%; p = 0.295), especially in patients without planned angiographic follow-up (5.2% vs. 4.9%; p = 0.896). The cost-effectiveness of ZES and PES was similar. CONCLUSIONS: After 2 years of follow-up, ZES demonstrated efficacy and cost-effectiveness comparable to PES, with fewer MIs and a trend toward less VLST. (The ENDEAVOR IV Clinical Trial: A Trial of a Coronary Stent System in Coronary Artery Lesions; NCT00217269).

PMID: 20129547 [PubMed - indexed for MEDLINE]

5.

JACC Cardiovasc Interv. 2009 Dec;2(12):1199-207.

Long-term clinical and economic analysis of the Endeavor zotarolimus-eluting stent versus the cypher sirolimus-eluting stent: 3-year results from the ENDEAVOR III trial (Randomized Controlled Trial of the Medtronic Endeavor Drug [ABT-578] Eluting Coronary Stent System Versus the Cypher Sirolimus-Eluting Coronary Stent System in De Novo Native Coronary Artery Lesions).

Eisenstein EL, Leon MB, Kandzari DE, Mauri L, Edwards R, Kong DF, Cowper PA, Anstrom KJ; ENDEAVOR III Investigators.

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Comment in:

- JACC Cardiovasc Interv. 2009 Dec;2(12):1236-9.

Abstract

OBJECTIVES: The aim of this study was to evaluate clinical and economic outcomes for subjects receiving zotarolimus-eluting (ZES) (n = 323) versus sirolimus-eluting stents (SES) (n = 113) in the ENDEAVOR III (Randomized Controlled Trial of the Medtronic Endeavor Drug [ABT-578] Eluting Coronary Stent System Versus the Cypher Sirolimus-Eluting Coronary Stent System in De Novo Native Coronary Artery Lesions) clinical trial. BACKGROUND: Although previous clinical trials have evaluated long-term clinical outcome for drug-eluting stents, none considered their economic implications. METHODS: We analyzed case report form information with quality-of-life adjustment and Medicare cost weights applied from secondary sources; compared differences in clinical outcomes, quality-adjusted survival, medical resource use, and medical costs; and evaluated cost-effectiveness through 3-year follow-up. RESULTS: The use of ZES versus SES reduced the 3-year rates/100 subjects of death or myocardial infarction (3.9 vs. 10.8; difference, -6.9; 95% confidence interval [CI]: -13.0 to 0.8; p = 0.028), with no difference in target vessel revascularization rates (17.9 vs. 12.2; difference, 5.7; 95% CI: -3.7 to 15.1; p = 0.23) but greater use of coronary artery bypass graft (CABG) surgery (3.5 vs. 0.0; difference 3.5; 95% CI: 1.3 to 5.7; p = 0.002). After discounting at 3% per annum, total medical costs for ZES versus SES were similar ($23,353 vs. $21,657; difference, $1,696; 95% CI: -$1,089 to $4,482, p = 0.23), and the 3-year cost-effectiveness ratio was $57,002/quality-adjusted life year. CONCLUSIONS: Despite a reduction in death or myocardial infarction and no difference in total revascularizations, medical costs were not decreased due to increased CABG repeat revascularization procedures for subjects receiving ZES versus SES. If future trials observe similar differences, improved safety with no difference in medical costs, the use of ZES versus SES will be a clinically and economically attractive treatment strategy. (The Medtronic Endeavor III Drug Eluting Coronary Stent System Clinical Trial [ENDEAVOR III]; NCT00217256).

PMID: 20129546 [PubMed - indexed for MEDLINE]

6.

JACC Cardiovasc Interv. 2009 Dec;2(12):1190-8.

3-year clinical follow-up of the XIENCE V everolimus-eluting coronary stent system in the treatment of patients with de novo coronary artery lesions: the SPIRIT II trial (Clinical Evaluation of the Xience V Everolimus Eluting Coronary Stent System in the Treatment of Patients with de novo Native Coronary Artery Lesions).

Garg S, Serruys P, Onuma Y, Dorange C, Veldhof S, Miquel-Hébert K, Sudhir K, Boland J, Huber K, Garcia E, te Riele JA; SPIRIT II Investigators.

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Comment in:

- JACC Cardiovasc Interv. 2009 Dec;2(12):1236-9.

Abstract

OBJECTIVES: This paper reports the 3-year clinical outcomes of the XIENCE V (Abbott Vascular, Santa Clara, California) everolimus-eluting stent (EES) compared with the TAXUS (Boston Scientific, Natick, Massachusetts) paclitaxel-eluting stent (PES) in the randomized SPIRIT II (Clinical Evaluation of the Xience V Everolimus Eluting Coronary Stent System in the Treatment of Patients with de novo Native Coronary Artery Lesions) study. BACKGROUND: The Xience V EES is a new-generation drug-eluting stent (DES) that might offer advantages over the first-generation DES in terms of improved clinical outcomes and a better safety profile. METHODS: The SPIRIT II trial was a multicenter, prospective, randomized, single-blind, clinical trial, randomizing 300 patients with de novo coronary artery lesions in a ratio of 3:1 to either EES or PES. The primary end point was in-stent late loss at 180 days. RESULTS: At 3-year clinical follow-up cardiac death was numerically lower with EES than PES (0.5% vs. 4.3%, p = 0.056). The observed rate of myocardial infarction was 3.6% for EES and 7.2% for PES (p = 0.31). The rate of ischemia-driven target lesion revascularization was 4.6% and 10.1% for EES and PES, respectively (p = 0.14). Overall, there was a trend for lower major adverse cardiovascular events in the EES group compared with PES (7.2% vs. 15.9%, p = 0.053).(Myrsini's note: none of these 'improved" clinical outcomes has reached statistical significance) The rate of stent thrombosis was low and comparable in both groups (EES 1.0% vs. PES 2.9%). CONCLUSIONS: The present study reports the favorable 3-year clinical outcomes of the EES, which are consistent with the results from other studies of the EES with shorter follow-up.

PMID: 20129545 [PubMed - indexed for MEDLINE]

7.

Am J Cardiol. 2010 Jan 1;105(1):64-8. Epub 2009 Nov 14.

Meta-analysis of five randomized clinical trials comparing sirolimus- versus paclitaxel-eluting stents in patients with diabetes mellitus.

Zhang F, Dong L, Ge J.

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Abstract

Recent data on drug-eluting stents have shown improved clinical outcomes in patients with diabetes mellitus. However, the relative efficacy and safety of sirolimus-eluting stents (SES) compared with paclitaxel-eluting stents (PES) remains controversial. Therefore, a meta-analysis of randomized trials was performed to compare SES with PES exclusively in patients with diabetes. The published research was scanned by formal searches of electronic databases (PubMed, EMBASE and the Cochrane Central Register of Controlled Trials) from January 2001 to April 2009. All randomized trials involving head-to-head comparison of SES versus PES in patients with diabetes were examined for analysis. A total of 5 randomized trials were included in the present meta-analysis, involving 1,173 patients (594 in the SES group, 579 in the PES group). SES were significantly more effective in the reduction of target lesion revascularization (5.1% vs 11.4%, odds ratio [OR] 0.41, 95% confidence interval [CI] 0.26 to 0.64, p <0.001) and angiographic binary (> or =50%) restenosis (5.6% vs 16.4%, OR 0.30, 95% CI 0.19 to 0.48, p <0.001) compared to PES. In contrast, the differences between SES and PES were not statistically significant with respect to cardiac death (2.2% vs 2.9%, OR 0.71, 95% CI 0.34 to 1.47, p = 0.35), myocardial infarction (1.5% vs 2.6%, OR 0.58, 95% CI 0.26 to 1.31, p = 0.19), and stent thrombosis (0.6% vs 1.2%, OR 0.57, 95% CI 0.18 to 0.84, p = 0.35). In conclusion, SES are superior to PES in reducing the incidences of restenosis and target lesion revascularization in patients with diabetes, with nonsignificant differences in terms of cardiac death, myocardial infarction, and stent thrombosis.

PMID: 20102892 [PubMed - indexed for MEDLINE]

8.

Circ Cardiovasc Interv. 2009 Aug;2(4):339-47. Epub 2009 Jul 22.

Two-year clinical, angiographic, and intravascular ultrasound follow-up of the XIENCE V everolimus-eluting stent in the treatment of

patients with de novo native coronary artery lesions: the SPIRIT II trial.

Claessen BE, Beijk MA, Legrand V, Ruzyllo W, Manari A, Varenne O, Suttorp MJ, Tijssen JG, Miquel-Hebert K, Veldhof S, Henriques JP, Serruys PW, Piek JJ.

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Abstract

BACKGROUND: This article reports the 2-year clinical, angiographic, and intravascular ultrasound outcomes of the everolimus-eluting stent (EES) compared with the paclitaxel-eluting stent (PES) in the randomized SPIRIT II trial. METHODS AND RESULTS: This was a prospective, single-blind clinical trial in which a total of 300 patients with de novo native coronary artery lesions were randomized to either EES or PES in a 3:1 fashion. Clinical follow-up was planned at 2 years in all patients. A subset of 152 patients underwent serial angiographic and intravascular ultrasound analyses at 6 months and 2 years. After 2 years, target lesion failure (cardiac death, myocardial infarction, and ischemia-driven target lesion revascularization) rates were 6.6% and 11% in EES and PES, respectively (P=0.31). At 6 months, a significant reduction in angiographic in-stent late loss and percentage volume obstruction measured by intravascular ultrasound was observed in the EES group. However, at 2-year follow-up, a late increased intimal hyperplasia growth after implantation of an EES was observed. There were no significant differences between EES and PES for in-stent late loss (EES, 0.33+/-0.37 mm versus PES, 0.34+/-0.34 mm; P=0.84) and percentage volume obstruction (EES, 5.18+/-6.22% versus PES, 5.80+/-6.31%; P=0.65) at 2 years. The incidence of stent thrombosis was low and comparable in both groups (EES, 0.9%; PES, 1.4%). CONCLUSIONS: Although the previously reported angiographic and clinical superiority of the EES has vanished over time, this report confirms and extends the previously demonstrated noninferiority in terms of in-stent late loss of the EES when compared with the PES up to 2-year follow-up. There were no significant differences between EES and PES in clinical, angiographic and intravascular ultrasound outcomes at 2 years.

PMID: 20031737 [PubMed - indexed for MEDLINE]

9.

Circ Cardiovasc Interv. 2009 Jun;2(3):188-95. Epub 2009 May 8.

Randomized comparison of the Nobori Biolimus A9-eluting coronary stent with the Taxus Liberté paclitaxel-eluting coronary stent in patients with stenosis in native coronary arteries: the NOBORI 1 trial--Phase 2.

Chevalier B, Silber S, Park SJ, Garcia E, Schuler G, Suryapranata H, Koolen J, Hauptmann KE, Wijns W, Morice MC, Carrie D, van Es GA, Nagai H, Detiege D, Paunovic D, Serruys PW; NOBORI 1 Clinical Investigators.

Collaborators (47)
Chevalier B, Serruys PW, Garcia E, Silber S, Suryapranata H, Nagai H, Schuijer M, Paunovic D, Boersma E, Rensing B, Smits P, Vos J, Danzi GB, Urban P, Reimers B, Hanet C, Vranckx P, Worthley S, Wijns W, Legrand V, Erard K, Thuesen L, Chevalier B, Fajadet J, Teiger E, Morice MC, Hamon M, Garot P, Carrie D, Silber S, Reifart N, Hamm C, Nowak B, Schiele T, Schuler G, Hauptmann K, Park SJ, Koolen J, Ziekenhuis C, Suryapranata H, Serruys P, Garcia E, Marañón G, Serra A, Thomas M, Fath-Ordoubadi F, Hildick-Smith D.

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Abstract

BACKGROUND: The newly developed Nobori (TERUMO)coronary stent coated with a bioresorbable polymer, polylactic acid, and the antiproliferative agent Biolimus A9 has the potential to reduce restenosis by suppressing neointima formation. METHODS AND RESULTS: We conducted a randomized (2:1), controlled trial comparing the Biolimus A9-eluting stent Nobori and the paclitaxel-eluting stent Taxus Liberté (Boston Scientific), in 243 patients (153 Nobori and 90 Taxus) at 29 centers in Europe, Asia, and Australia. Patients with previously untreated lesions in up to 2 native coronary arteries were considered for enrollment. The primary end point was in-stent late loss at 9 months, whereas secondary end points included other quantitative coronary angiography parameters, such as in-segment late loss and the rate of restenosis as well as key intravascular ultrasound parameters. Clinical secondary end points were stent thrombosis and composite of major adverse cardiac events comprising death, myocardial infarction, and target vessel revascularization. At 9 months, the in-stent late loss was significantly lower in the Nobori group compared with the Taxus group (0.11+/-0.30 mm versus 0.32+/-0.50 mm) reaching both the primary hypothesis of noninferiority of Nobori stent versus Taxus Liberté stent (P<0.001) and the secondary hypothesis of superiority (P=0.001). This finding was confirmed by a significant reduction in binary restenosis from 6.2% in Taxus to 0.7% in Nobori (P=0.02) and neointimal volume obstruction, detected by intravascular ultrasound, from 5.5+/-7.2% in Taxus to

1.8+/-5.2% in Nobori (P=0.01). The major adverse cardiac events rate was 4.6% in the Nobori and 5.6% in the Taxus cohort of patients. The stent thrombosis rate was 0% in the Nobori arm and 4.4% in the Taxus arm. CONCLUSIONS: The NOBORI 1 clinical trial confirmed its primary hypothesis--noninferiority of the Nobori Biolimus A9-eluting stent versus the Taxus Liberté stent in reducing neointimal proliferation. Both stents showed a low major adverse cardiac events rate in the studied population.

PMID: 20031715 [PubMed - indexed for MEDLINE]

10.

Am Heart J. 2009 Dec;158(6):1005-10.

Clinical and angiographic comparison of everolimus-eluting and paclitaxel-eluting stents in small coronary arteries: a post hoc analysis of the SPIRIT III randomized trial.

Hermiller JB, Fergus T, Pierson W, Su X, Sood P, Sudhir K, Stone GW.

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Abstract

BACKGROUND: Drug-eluting stents with low late loss may be particularly beneficial in small coronary arteries. We therefore examined whether the everolimus-eluting stent is superior to the paclitaxel-eluting stent in patients treated with 2.5-mm stents in the SPIRIT III trial. METHODS: The SPIRIT III trial was a prospective, multicenter, randomized (2:1; XIENCE V (ABBOT): TAXUS Express (Boston Scientific) trial in which 1002 patients were enrolled. One or more 2.5-mm stents were implanted in 160 patients in the XIENCE V arm, and 59 patients, in the TAXUS arm. Mean vessel diameter was 2.36 +/- 0.30 and 2.34 +/- 0.33 mm in the XIENCE V and TAXUS groups, respectively (P = .69). RESULTS: At 9 months, XIENCE V compared to TAXUS reduced the rates of major adverse cardiac events (cardiac death, myocardial infarction, or ischemic target lesion revascularization) from 12.5% to 3.2% (P = .02) and target vessel failure (cardiac death, reinfarction, or ischemic target vessel revascularization) from 16.1% to 5.2% (P = .02), the differences being driven primarily by reductions in target lesion revascularization (12.5% vs 1.3%; P = .002). In-stent late loss was significantly reduced by XIENCE V when compared to TAXUS (0.54 +/- 0.74 vs 0.11 +/- 0.43 mm, P = .01), as was In-segment binary angiographic restenosis

(20.8% vs 4.1%, P = .02). CONCLUSIONS: In this post hoc analysis from the SPIRIT III trial, the XIENCE V 2.5-mm stent significantly reduced clinical and angiographic restenosis compared to the TAXUS 2.5-mm stent, further supporting the hypothesis that lower late loss is beneficial in small vessel disease.

PMID: 19958868 [PubMed - indexed for MEDLINE]

11.

Am J Cardiol. 2009 Nov 15;104(10):1370-6. Epub 2009 Sep 26.

Comparison of the efficacy and safety of zotarolimus-, sirolimus-, and paclitaxel-eluting stents in patients with ST-elevation myocardial infarction.

Lee CW, Park DW, Lee SH, Kim YH, Hong MK, Kim JJ, Park SW, Yun SC, Seong IW, Lee JH, Lee NH, Cho YH, Cheong SS, Lim DS, Yang JY, Lee SG, Kim KS, Yoon J, Jeong MH, Seung KB, Hong TJ, Park SJ; ZEST-AMI Investigators.

Department of Cardiology, Center for Medical Research and Information, University of Ulsan College of Medicine, Asan Medical Center, Seoul, Korea.

Abstract

Drug-eluting stents (DESs) are increasingly used for treatment of acute ST-segment elevation myocardial infarction (STEMI), but there are few comparisons of outcomes of various types of DES. We compared the efficacy and safety of zotarolimus-eluting stents (ZESs), sirolimus-eluting stents (SESs), and paclitaxel-eluting stents (PESs) in primary intervention for STEMI. This multicenter, prospectively randomized ZEST-AMI trial included 328 patients at 12 medical centers who were randomly assigned to ZES (n = 108), SES (n = 110), or PES (n = 110) deployment. The primary end point was major adverse cardiac events (death, MI, and ischemia-driven target vessel revascularization) at 12 months. Secondary end points included the individual components of the primary end point, late loss, angiographic restenosis, and stent thrombosis. Baseline clinical and angiographic characteristics were well matched. In-segment late loss (0.28 +/- 0.42 vs 0.46 +/- 0.48 vs 0.47 +/- 0.50 mm, respectively, p = 0.029) and restenosis rate (2.7% vs 15.9% vs 12.3%, respectively, p = 0.027) at 8 months were lowest in the SES group compared to the ZES and PES groups. At 12 months, cumulative incidence rates of

primary end points in the ZES, SES, and PES groups were 11.3%, 8.2%, and 8.2%, respectively (p = 0.834) . There were 2 acute (in the SES group) and 5 subacute (2 in the SES group and 3 in the PES group) stent thromboses. Incidence of death, recurrent MI, or ischemia-driven target vessel revascularization did not differ among the 3 groups. In conclusion, despite the difference in restenosis rate, the efficacy and safety of the 3 different DESs showed similar, acceptable results in the treatment of STEMI.

PMID: 19892052 [PubMed - indexed for MEDLINE]

12.

JACC Cardiovasc Interv. 2009 Oct;2(10):967-76.

Clinical and angiographic outcomes in diabetics from the ENDEAVOR IV trial: randomized comparison of zotarolimus- and paclitaxel-eluting stents in patients with coronary artery disease.

Kirtane AJ, Patel R, O'Shaughnessy C, Overlie P, McLaurin B, Solomon S, Mauri L, Fitzgerald P, Popma JJ, Kandzari DE, Leon MB.

Columbia University Medical Center and the Cardiovascular Research Foundation, New York, New York, USA.

Abstract

OBJECTIVES: The aim of this study was to examine outcomes related to the use of the Endeavor zotarolimus-eluting stent (ZES) (Medtronic CardioVascular, Santa Rosa, California) compared with the TAXUS paclitaxel-eluting stent (PES) (Boston Scientific Corp., Natick, Massachusetts) in the 477 patients with diabetes mellitus (DM) enrolled in the randomized ENDEAVOR IV (Randomized Comparison of Zotarolimus- and Paclitaxel-Eluting Stents in Patients with Coronary Artery Disease) trial. BACKGROUND: Percutaneous coronary intervention (PCI) in diabetic patients is associated with increased rates of restenosis-related end points compared with PCI in nondiabetic patients. Although ZES has been associated with similar clinical efficacy compared with PES in the overall trial population of the ENDEAVOR IV trial, whether these results are maintained in the higher-risk restenosis subgroup of patients with DM has not been determined. METHODS: Clinical and angiographic outcomes were compared according to randomized treatment assignment to either ZES or PES. RESULTS: Baseline

characteristics were similar among ZES (n = 241) and PES (n = 236) diabetic patients, with slightly longer lesion lengths in PES-treated patients (12.9 mm vs. 14.0 mm, p = 0.041). Among the 86 DM patients assigned to routine angiographic follow-up (18% of the overall DM cohort), in-stent percent diameter stenosis at 8 months was greater among ZES-treated patients (32.9 vs. 21.1, p = 0.023), with a trend toward higher in-stent late loss. One-year clinical outcomes were similar among DM patients treated with either ZES or PES (target vessel failure: 8.6% vs. 10.8%, p = 0.53; target lesion revascularization: 6.9% vs. 5.8%, p = 0.70; target vessel revascularization: 8.6% vs. 9.4%, p = 0.87). There were no significant interactions between DM status and stent type with respect to the outcomes measured, and the relative efficacy/safety of ZES and PES were similar among insulin- and noninsulin-requiring subgroups. CONCLUSIONS: One-year clinical outcomes were similar among DM patients treated with ZES and PES in the ENDEAVOR IV trial. These findings parallel the overall trial results, which demonstrated similar efficacy and safety of ZES and PES for single de novo coronary lesions.

PMID: 19850257 [PubMed - indexed for MEDLINE]

13.

JACC Cardiovasc Interv. 2009 Sep;2(9):861-70.

Impact of vessel size on angiographic and clinical outcomes of revascularization with biolimus-eluting stent with biodegradable polymer and sirolimus-eluting stent with durable polymer the LEADERS trial substudy.

Wykrzykowska JJ, Serruys PW, Onuma Y, de Vries T, van Es GA, Buszman P, Linke A, Ischinger T, Klauss V, Corti R, Eberli F, Wijns W, Morice MC, di Mario C, van Geuns RJ, Juni P, Windecker S.

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Abstract

OBJECTIVES: We assessed the impact of vessel size on outcomes of stenting with biolimus-eluting degradable polymer stent (BES) and sirolimus-eluting permanent polymer stent (SES) within a randomized multicenter trial (LEADERS). BACKGROUND: Stenting of small vessels might be associated with higher rates of adverse events. METHODS: "All-comer" patients (n = 1,707) were

randomized to BES and SES. Post-hoc-stratified analysis of angiographic and clinical outcomes at 9 months and 1 year, respectively, was performed for vessels with reference diameter <or=2.75 mm versus >2.75 mm. RESULTS: Of 1,707 patients, 429 patients in the BES group with 576 lesions and 434 patients in the SES group with 557 lesions had only small vessels treated (50.6% of the patient cohort). In patients with small vessels there was no significant difference in overall major adverse cardiac events (MACE) rate (12.1% vs. 11.8%; p = 0.89) or target lesion revascularization (TLR) rate (9.6% vs. 7.4%; p = 0.26) between BES and SES. The MACE and TLR rates in the small-vessel patient population were higher than in the large-vessel population. The TLR rate was 9.6% versus 2.6%, and MACE rate was 12.1% versus 7.1% for small versus large vessels in the BES arm (TLR: hazard ratio [HR] = 3.724, p = 0.0013; MACE: HR = 1.720, p = 0.0412). In the SES arm, TLR was 7.4% versus 5.1%, and MACE was 11.8% versus 10.3% in small versus large vessels (TLR: HR = 1.435, p = 0.2594; MACE: HR = 1.149, p = 0.5546). CONCLUSIONS: Prevalence of small vessel disease is high in an "all-comer" population with higher TLR and MACE rates. The BES and SES seem equivalent in treatment outcomes of small vessels in this "all-comer" patient population.

PMID: 19778775 [PubMed - indexed for MEDLINE]

14.

EuroIntervention. 2009 Aug;5(3):310-7.

Biolimus-eluting biodegradable polymer versus sirolimus-eluting permanent polymer stent performance in long lesions: results from the LEADERS multicentre trial substudy.

Wykrzykowska JJ, Räber L, de Vries T, Bressers M, Buszman P, Linke A, Ischinger T, Klauss V, Eberli F, Corti R, Wijns W, Morice MC, di Mario C, Regar E, Jüni P, Windecker S, Serruys PW.

The Department of Interventional Cardiology Thoraxcenter, Erasmus MC, Rotterdam, The Netherlands.

Abstract

AIMS: Lesion length remains a predictor of target lesion revascularisation and results of long lesion stenting remain poor. Sirolimus-eluting stents have been shown to perform better than paclitaxel eluting stents in long lesions. In this substudy of the LEADERS trial, we compared the performance of biolimus biodegradable polymer (BES) and sirolimus permanent polymer stents (SES) in long lesions.

METHODS AND RESULTS: A total of 1,707 'all-comer' patients were randomly allocated to treatment with BES and SES. A stratified analysis of angiographic and clinical outcomes at nine months and one year, respectively was performed for vessels with lesion length <20 mm versus >20 mm (as measured by quantitative angiography).Of 1,707 patients, 592 BES patients with 831 lesions and 619 SES patients with 876 lesions had only short lesions treated. One hundred and fifty-three BES patients with 166 lesions and 151 SES patients with 162 lesions had long lesions. There were no significant differences in baseline clinical characteristics, except for higher number of patients with long lesions presenting with acute myocardial infarction in both stent groups. Long lesions tended to have lower MLD and greater percent diameter stenosis at baseline than short lesions. Late loss was greater for long lesions than short lesions. There was no statistically significant difference in late loss between BES and SES stents (0.32+/-0.69 vs 0.24+/-0.57, p=0.59). Binary in-segment restenosis was present in 23.2% versus 13.1% of long lesions treated with BES and SES, respectively (p=0.042). In patients with long lesions, the overall MACE rate was similar for BES and SES (17% vs 14.6%; p=0.62). There was a trend towards higher overall TLR rate with BES (12.4 % vs 6.0%; HR=2.06; p=0.07) and clinically driven TLR (10.5% vs 5.3%: HR 1.94; p=0.13). Rates of definite stent thrombosis were 3.3% in the long lesion group and 1.3-1.7 % in the short lesion group. CONCLUSIONS: BES and SES appear similar with respect to MACE in long lesions in this "all-comer" patient population. However, long lesions tended to have a higher rate of binary in-segment restenosis and TLR following BES than SES treatment.

PMID: 19736154 [PubMed - indexed for MEDLINE]

15.

Ann Med. 2009;41(8):599-607.

Two-year follow-up after percutaneous coronary intervention with titanium-nitride-oxide-coated stents versus paclitaxel-eluting stents in acute myocardial infarction.

Karjalainen PP, Ylitalo A, Niemelä M, Kervinen K, Mäkikallio T, Pietilä M, Sia J, Tuomainen P, Nyman K, Airaksinen KE.

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Abstract

BACKGROUND AND AIMS: The aim of this study was to evaluate the long-term effects of the titanium-nitride-oxide-coated (TITANOX) stent and the paclitaxel-eluting stent (PES) in patients who had undergone a percutaneous coronary intervention for acute myocardial infarction (MI). METHODS AND RESULTS: The TITAX-AMI trial randomly assigned 425 patients with MI to receive either a TITANOX stent or a PES. The primary end-point was a composite of MI, target lesion revascularization, or death from cardiac causes. At 12 months, there was no significant difference between patients receiving TITANOX stent or PES in the rate of primary end-point (10.3% versus 12.8%, P=0.5). After 2 years of follow-up, a significantly lower rate of primary end-point was observed in the TITANOX stent group compared with the PES group (11.2% versus 21.8%, HR 2.2, 95% confidence interval (CI) 1.3-3.8, P=0.004). This difference was driven by a reduced rate of MI (5.1% versus 15.6%, P<0.001) and cardiac death (0.9% versus 4.7%, P=0.02) in favour of the TITANOX stent. Definite stent thrombosis occurred in 0.5% and 6.2% of the patients (P=0.001), respectively. CONCLUSIONS: The implantation of a TITANOX stent resulted in better clinical outcome compared with a PES during 2 years of follow-up among patients treated for acute MI.

PMID: 19701826 [PubMed - indexed for MEDLINE]

16.

Heart. 2009 Sep;95(18):1489-94. Epub 2009 Jul 9.

Randomised trial of three rapamycin-eluting stents with different coating strategies for the reduction of coronary restenosis: 2-year follow-up results.

Byrne RA, Kufner S, Tiroch K, Massberg S, Laugwitz KL, Birkmeier A, Schulz S, Mehilli J; ISAR-TEST-3 Investigators.

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Comment in:

- Heart. 2010 Apr;96(8):630; author reply 630.

Abstract

BACKGROUND: Drug-eluting stent (DES) platforms devoid of durable polymer have potential to enhance long-term safety outcomes. The ISAR-TEST-3 study was a randomised trial comparing three rapamycin-eluting stents with different coating strategies. The present study examined 2-year outcomes of these patients and is the first large-scale trial to report longer-term outcomes with biodegradable polymer and polymer-free DES. METHODS: Patients with de novo coronary lesions in native vessels were randomly assigned to receive biodegradable polymer (BP; n = 202), permanent polymer (PP; Cypher; n = 202) and polymer-free (PF; n = 201) stents. The 2-year endpoints of interest were target lesion revascularisation (TLR), death/myocardial infarction (MI), stent thrombosis and delayed angiographic late luminal loss (LLL) between 6-8 months and 2 years. RESULTS: There were no significant differences in TLR (8.4%, 10.4% and 13.4% for BP, PP and PF stents, respectively; p = 0.19), death/MI (5.9%, 6.4% and 6.5% with BP, PP and PF respectively; p = 0.97) or stent thrombosis (definite/probable 0.5%, 1.0% and 1.0% with BP, PP and PF, respectively; p = 0.82). Paired angiographic follow-up at 6-8 months and 2 years was available for 302 patients (69.0% of eligible patients). Delayed LLL was significantly different across the treatment groups: 0.17 (0.42) mm, 0.16 (0.41) mm and -0.01 (0.36) mm for BP, PP and PF stents, respectively (p<0.001). CONCLUSION: Clinical antirestenotic efficacy was maintained with all three platforms between 1 and 2 years, although angiographic surveillance showed ongoing delayed LLL with both BP and PP stent platforms. At 2 years there was no signal of a differential safety profile between the three stent platforms.

17.

JACC Cardiovasc Interv. 2008 Oct;1(5):524-32.

A randomized, controlled, multicenter trial to evaluate the safety and efficacy of zotarolimus- versus paclitaxel-eluting stents in de novo occlusive lesions in coronary arteries The ZoMaxx I trial.

Chevalier B, Di Mario C, Neumann FJ, Ribichini F, Urban P, Popma JJ, Fitzgerald PJ, Cutlip DE, Williams DO, Ormiston J, Grube E, Whitbourn R, Schwartz LB; ZoMaxx I Investigators.

Centre Cardiologique du Nord, Saint-Denis, France.

Comment in:

- JACC Cardiovasc Interv. 2008 Oct;1(5):533-4.

Abstract

OBJECTIVES: A novel zotarolimus-eluting coronary stent system (ZoMaxx, Abbott Laboratories, Abbott Park, Illinois) was compared with a paclitaxel-eluting coronary stent (Taxus Express2 (Boston Scientific) in a randomized trial of percutaneous intervention for de novo coronary artery stenosis. The primary end point was defined as noninferiority of in-segment late lumen loss after 9 months. BACKGROUND: The ZoMaxx stent system elutes 10 microg/mm zotarolimus using a phosphorylcholine polymer loaded onto a novel stainless steel stent platform containing a 0.0007-inch inner layer of tantalum. METHODS: Twenty-nine investigative sites in Europe, Australia, and New Zealand enrolled 401 patients, 396 of whom received a study stent. RESULTS: After 9 months, late lumen loss was significantly greater in the ZoMaxx group (in-stent 0.67 +/- 0.57 mm vs. 0.45 +/- 0.48 mm; p < 0.001; in-segment 0.43 +/- 0.60 mm vs. 0.25 +/- 0. 45 mm; p = 0.003), resulting in significantly higher rates of >50% angiographic restenosis (in-stent 12.9% vs. 5.7%; p = 0.03; in-segment 16.5% vs. 6.9%; p = 0.007). The upper bound of the 95% confidence interval on the difference in in-segment late lumen loss between the 2 treatment groups (0.27 mm) exceeded the 0.25 mm value pre-specified for noninferiority. There were no significant differences between ZoMaxx and Taxus-treated groups with respect to target lesion revascularization (8.0% vs. 4.1%; p = 0.14), major adverse cardiac events (12.6% vs. 9.6%; p = 0.43), or stent thrombosis (0.5% in both groups). CONCLUSIONS: After 9 months, the ZoMaxx stent showed less neointimal inhibition than the Taxus stent, as shown by higher in-stent late loss and restenosis by qualitative coronary angiography.

18.

J Am Coll Cardiol. 2009 May 12;53(19):1760-8.

Paclitaxel- versus sirolimus-eluting stents for unprotected left main coronary artery disease.

Mehilli J, Kastrati A, Byrne RA, Bruskina O, Iijima R, Schulz S, Pache J, Seyfarth M, Massberg S, Laugwitz KL, Dirschinger J, Schömig A; LEFT-MAIN Intracoronary Stenting and Angiographic Results: Drug-Eluting Stents for Unprotected Coronary Left Main Lesions Study Investigators.

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Comment in:

- J Am Coll Cardiol. 2009 May 12;53(19):1769-72.

Abstract

OBJECTIVES: The aim of this trial was to compare the safety and efficacy of paclitaxel-eluting stents (PES) and sirolimus-eluting stents (SES) for treatment of unprotected left main coronary artery (uLMCA) disease. BACKGROUND: Both PES and SES have reduced the risk of restenosis, particularly in high-risk patient and lesion subsets. However, their comparative performance in uLMCA lesions is not known. METHODS: In this randomized study, 607 patients with symptomatic coronary artery disease undergoing percutaneous coronary intervention for uLMCA were enrolled: 302 were assigned to receive a PES (Taxus, Boston Scientific, Natick, Massachusetts) and 305 assigned to receive a SES (Cypher, Cordis, Johnson & Johnson, New Brunswick, New Jersey). The primary end point was the combined incidence of death, myocardial infarction, and target lesion revascularization (TLR) at 1 year. The secondary end point was angiographic restenosis on the basis of the LMCA area analysis at follow-up angiography. RESULTS: At 1 year the cumulative incidence of death, myocardial infarction, or TLR was 13.6% in the PES and 15.8% in the SES group (relative risk [RR]: 0.85, 95% confidence interval [CI]: 0.56 to 1.29, p = 0.44). One patient in the PES group (0.3%) and 2 patients in the SES group (0.7%) experienced definite stent thrombosis (p = 0.57). Mortality at 2 years was 10.7% in the PES and 8.7% in the SES group (RR: 1.14, 95% CI: 0.66 to 1.95, p = 0.64). Angiographic restenosis was 16.0% with PES and 19.4% with SES (RR: 0.82, 95% CI: 0.57 to 1.19, p = 0.30). CONCLUSIONS: Implantation of either PES or SES in uLMCA lesions is safe and effective; both of these drug-eluting stents provide comparable clinical and angiographic outcomes. (Drug-Eluting-Stents for Unprotected Left Main Stem Disease [ISAR-LEFT-MAIN]; NCT00133237).

PMID: 19422982 [PubMed - indexed for MEDLINE]

- 19.

Eur Heart J. 2009 Apr;30(8):923-31. Epub 2009 Feb 24.

A polymer-free dual drug-eluting stent in patients with coronary artery disease: a randomized trial vs. polymer-based drug-eluting stents.

Byrne RA, Mehilli J, Iijima R, Schulz S, Pache J, Seyfarth M, Schömig A, Kastrati A.

ISAR Centre, Deutsches Herzzentrum, Technische Universität, Lazarettstrasse 36, 80636 Munich, Germany.

Abstract

AIMS: Long-term polymer residue in the coronary milieu is a consequence of current drug-eluting stent (DES) therapy and has been implicated in late adverse events. We developed a novel polymer-free rapamycin- and probucol-eluting stent (Dual-DES) and compared its efficacy against commercially available permanent polymer-based sirolimus-eluting (SES; Cypher Cordis, J&J) and zotarolimus-eluting (ZES; Endeavor Medtronic) stents. METHODS AND RESULTS: Between March 2006 and July 2007, a total of 1007 patients undergoing coronary stenting of de novo lesions, in native vessels, were randomized to treatment with SES (n = 335), Dual-DES (n = 333), or ZES (n = 339). The primary endpoint was binary angiographic restenosis at 6-8 month follow-up angiography. Secondary endpoints were angiographic in-stent late loss; and target lesion revascularization (TLR), death/myocardial infarction and stent thrombosis at 12 months. Follow-up angiographic data were available for 828 (82.2%) patients. There was a significant difference in both binary restenosis and TLR across treatment groups (P = 0.003 and P < 0.001, respectively). Binary restenosis in the Dual-DES group (11.0%) was significantly lower than that in the ZES group (19.3%; P = 0.002) but comparable with that in the SES group (12.0%; P = 0.68). Similarly, TLR with Dual-DES (6.8%) was significantly lower than ZES (13.6%; P = 0.001) but not different to that of SES (7.2%; P = 0.83). These differences were mirrored in the extent of late loss across the groups. No differences were observed between stent groups in terms of death/myocardial infarction or stent thrombosis. CONCLUSION: A novel polymer-free Dual-DES is associated with high anti-restenotic efficacy without recourse to carrier polymer. Potential long-term clinical advantage of this platform remains subject to investigation. Study registered at ClinicalTrials.gov. Identifier number: NCT00332397.

PMID: 19240066 [PubMed - indexed for MEDLINE]Free Article

20.

Circulation. 2009 Feb 10;119(5):680-6. Epub 2009 Jan 26.

Randomized comparison of everolimus-eluting and paclitaxel-eluting stents: two-year clinical follow-up from the Clinical Evaluation of the Xience V Everolimus Eluting Coronary Stent System in the Treatment

of Patients with de novo Native Coronary Artery Lesions (SPIRIT) III trial.

Stone GW, Midei M, Newman W, Sanz M, Hermiller JB, Williams J, Farhat N, Caputo R, Xenopoulos N, Applegate R, Gordon P, White RM, Sudhir K, Cutlip DE, Petersen JL; SPIRIT III Investigators.

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Comment in:

- Circulation. 2009 Feb 10;119(5):653-6.

Abstract

BACKGROUND: In the prospective randomized Clinical Evaluation of the Xience V Everolimus Eluting Coronary Stent System Abbott in the Treatment of Patients with de novo Native Coronary Artery Lesions (SPIRIT) III trial, an everolimus-eluting stent (EES) compared with a widely used paclitaxel-eluting stent (PES) resulted in a statistically significant reduction in angiographic in-segment late loss at 8 months and noninferior rates of target vessel failure (cardiac death, myocardial infarction, or target vessel revascularization) at 1 year. The safety and efficacy of EES after 1 year have not been reported. METHODS AND RESULTS: A total of 1002 patients with up to 2 de novo native coronary artery lesions (reference vessel diameter, 2.5 to 3.75 mm; lesion length < or =28 mm) were randomized 2:1 to EES versus PES. Antiplatelet therapy consisted of aspirin indefinitely and a thienopyridine for > or =6 months. Between 1 and 2 years, patients treated with EES compared with PES tended to have fewer episodes of protocol-defined stent thrombosis (0.2% versus 1.0%; P=0.10) and myocardial infarctions (0.5% versus 1.7%; P=0.12), with similar rates of cardiac death (0.3% versus 0.3%; P=1.0) and target vessel revascularization (2.9% versus 3.0%; P=1.0). As a result, at the completion of the 2-year follow-up, treatment with EES compared with PES resulted in a significant 32% reduction in target vessel failure (10.7% versus 15.4%; hazard ratio, 0.68; 95% confidence interval, 0.48 to 0.98; P=0.04) and a 45% reduction in major adverse cardiac events (cardiac death, myocardial infarction, or target lesion revascularization; 7.3% versus 12.8%; hazard ratio, 0.55; 95% confidence interval, 0.36 to 0.83; P=0.004). Among the 360 patients who discontinued clopidogrel or ticlopidine after 6 months, stent thrombosis subsequently developed in 0.4% of EES patients versus 2.6% of PES patients (P=0.10). CONCLUSIONS: Patients treated with EES rather than PES experienced significantly improved event-

free survival at a 2-year follow-up in the SPIRIT III trial, with continued divergence of the hazard curves for target vessel failure and major adverse cardiac events between 1 and 2 years evident. The encouraging trends toward fewer stent thrombosis episodes after 6 months in EES-treated patients who discontinued a thienopyridine and after 1 year in all patients treated with EES rather than PES deserve further study.


21.

Am J Cardiol. 2009 Feb 1;103(3):345-9. Epub 2008 Nov 12.

Comparison of the sirolimus-eluting versus paclitaxel-eluting coronary stent in patients with diabetes mellitus: the diabetes and drug-eluting stent (DiabeDES) randomized angiography trial.

Maeng M, Jensen LO, Galloe AM, Thayssen P, Christiansen EH, Hansen KN, Helqvist S, Botker HE, Lassen JF, Thuesen L.

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Abstract

The aim of the present study was to evaluate angiographic late luminal loss after the implantation of sirolimus-eluting Cypher stents Cordis, J&J and paclitaxel-eluting Taxus stents Boston Scientific in patients with diabetes. The study was a Danish multicenter, open-label, randomized trial. One hundred fifty-three patients with diabetes with coronary artery disease were randomized to Cypher (n = 76) or Taxus (n = 77) stent implantation. All patients were followed for 8 months. The primary end point was 8-month angiographic in-stent late luminal loss. This primary end point was reduced in the Cypher group compared with the Taxus group (0.23 +/- 0.54 vs 0.44 +/- 0.52 mm, p = 0.025). Angiographic in-segment restenosis at 8-month follow-up, a secondary end point, was present in 16 patients (Cypher, n = 6; Taxus, n = 10; p = 0.24). Target lesion revascularization was performed in 5 patients (6.5%) and 9 patients (11.8%) in the Cypher and Taxus groups, respectively (p = 0.25). Definite stent thrombosis was observed in 2 patients (in the Taxus group), no patients had probable stent thrombosis, and 1 patient in each group had possible stent thrombosis. Major adverse cardiac events (cardiac death, myocardial infarction, definite stent thrombosis, or target lesion revascularization) were observed in 17 patients (Cypher, n = 6; Taxus, n = 11; p = 0.19). In conclusion, angiographic in-stent late luminal loss is

significantly reduced in patients with diabetes by use of the sirolimus-eluting Cypher stent compared with the paclitaxel-eluting Taxus stent.

PMID: 19166687 [PubMed - indexed for MEDLINE]

- 22.

EuroIntervention. 2008 Aug;4(2):234-41.

Titanium-nitride-oxide coated stents versus paclitaxel-eluting stents in acute myocardial infarction: a 12-months follow-up report from the TITAX AMI trial.

Karjalainen PP, Ylitalo A, Niemelä M, Kervinen K, Mäkikallio T, Pietili M, Sia J, Tuomainen P, Nyman K, Airaksinen KE.

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Abstract

AIMS: The aim of this study was to evaluate the effectiveness of titanium-nitride-oxide (TITANOX)-coated stent and paclitaxel-eluting stent (PES) in patients presenting with acute myocardial infarction (MI). METHODS AND RESULTS: A total of 425 patients presenting with acute non-ST-elevation MI or ST-elevation MI were randomly assigned to receive TITANOX-coated stent or PES. The primary end point was a composite of MI, target lesion revascularisation (TLR) or death from cardiac causes. At 12 months, there was no significant difference between patients receiving TITANOX-coated stent or PES in the rates of primary end point (10.3% vs. 12.8%, P=0.5), MI (4.2% vs. 8.1%, P=0.1), or TLR (9.3% vs. 7.1%, P=0.5), respectively. The incidence of stent thrombosis, defined according to Academic Research Consortium classification, was significantly lower in the TITANOX group compared to the PES group (0.9% vs. 4.3%, P=0.03). CONCLUSIONS: TITANOX-coated stent and PES resulted in comparable clinical outcomes during 12 months follow-up among patients treated for acute MI.

PMID: 19110789 [PubMed - indexed for MEDLINE]

- 23.

Lancet. 2008 Sep 27;372(9644):1163-73. Epub 2008 Aug 31.

Biolimus-eluting stent with biodegradable polymer versus sirolimus-eluting stent with durable polymer for coronary revascularisation (LEADERS): a randomised non-inferiority trial.

Windecker S, Serruys PW, Wandel S, Buszman P, Trznadel S, Linke A, Lenk K, Ischinger T, Klauss V, Eberli F, Corti R, Wijns W, Morice MC, di Mario C, Davies S, van Geuns RJ, Eerdmans P, van Es GA, Meier B, Jüni P.

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Comment in:

- Lancet. 2008 Sep 27;372(9644):1126-8.

Abstract

BACKGROUND: A novel stent platform eluting biolimus, a sirolimus analogue, from a biodegradable polymer showed promising results in preliminary studies. We compared the safety and efficacy of a biolimus-eluting stent (with biodegradable polymer) with a sirolimus-eluting stent (with durable polymer).

METHODS: We undertook a multicentre, assessor-blind, non-inferiority study in ten European centres. 1707 patients aged 18 years or older with chronic stable coronary artery disease or acute coronary syndromes were centrally randomised by a computer-generated allocation sequence to treatment with either biolimus-eluting (n=857) or sirolimus-eluting (n=850) stents. The primary endpoint was a composite of cardiac death, myocardial infarction, or clinically-indicated target vessel revascularisation within 9 months. Analysis was by intention to treat. 427 patients were randomly allocated to angiographic follow-up, with in-stent percentage diameter stenosis as principal outcome measure at 9 months. The trial is registered with ClinicalTrials.gov, number NCT00389220. FINDINGS: We analysed all randomised patients. Biolimus-eluting stents were non-inferior to sirolimus-eluting stents for the primary endpoint at 9 months (79 [9%] patients vs 89 [11%], rate ratio 0.88 [95% CI 0.64-1.19], p for non-inferiority=0.003, p for superiority=0.39). Frequency of cardiac death (14 [1.6%] vs 21 [2.5%], p for superiority=0.22), myocardial infarction (49 [5.7%] vs 39 [4.6%], p=0.30), and clinically-indicated target vessel revascularisation (38 [4.4%] vs 47 [5.5%], p=0.29) were similar for both stent types. 168 (79%) patients in the biolimus-eluting group and 167 (78%) in the sirolimus-eluting group had data for angiographic follow-up available. Biolimus-eluting stents were non-inferior to sirolimus-eluting stents in

in-stent percentage diameter stenosis (20.9%vs 23.3%, difference -2.2% [95% CI -6.0 to 1.6], p for non-inferiority=0.001, p for superiority=0.26). INTERPRETATION: Our results suggest that a stent eluting biolimus from a biodegradable polymer represents a safe and effective alternative to a stent eluting sirolimus from a durable polymer in patients with chronic stable coronary artery disease or acute coronary syndromes. FUNDING: Biosensors Europe SA, Switzerland.


24.

Eur Heart J. 2008 Aug;29(16):1975-82. Epub 2008 Jun 11.

Randomized trial of three rapamycin-eluting stents with different coating strategies for the reduction of coronary restenosis.

Mehilli J, Byrne RA, Wieczorek A, Iijima R, Schulz S, Bruskina O, Pache J, Wessely R, Schömig A, Kastrati A; Intracoronary Stenting and Angiographic Restenosis Investigators--Test Efficacy of Rapamycin-eluting Stents with Different Polymer Coating Strategies (ISAR-TEST-3).

Deutsches Herzzentrum and 1. Medizinische Klinik rechts der Isar, Technische Universität, Lazarettstrasse 36, 80636 Munich, Germany.

Comment in:

- Eur Heart J. 2008 Aug;29(16):1930-1.

Abstract

AIMS: The objective of this study was to assess the non-inferiority, in terms of anti-restenotic efficacy, of both biodegradable-polymer (BP) and polymer-free (PF) stents compared with permanent-polymer rapamycin-eluting (PP; Cypher) stent. METHODS AND RESULTS: Patients with de novo coronary lesions in native vessels were randomly assigned to receive a BP stent, a PF stent or a PP stent. The primary endpoint was in-stent late lumen loss at follow-up angiogram. A total of 605 patients were enrolled: 202 patients received BP stents, 202 were treated with PP stents, and 201 received PF stents. Repeat angiography was available for 492 patients (81.3%). Mean late lumen loss at 6-8-month angiographic follow-up was 0.17 +/- 0.45 mm in the BP stent group, 0.23 +/- 0.46 mm in the PP cohort, and 0.47 +/- 0.56 mm in the PF stent group. The BP stent met pre-specified criteria for non-inferiority (P < 0.001), whereas the PF stent did not (P = 0.94). There were no differences in safety outcomes.

CONCLUSION: Both BP and PF stents have a 1-year safety profile similar to that of the PP stent. Whereas the PF stent provided an inferior efficacy, the BP stent is at least as effective as the PP stent in terms of anti-restenotic efficacy.

PMID: 18550554 [PubMed - indexed for MEDLINE]Free Article

25.

JAMA. 2008 Apr 23;299(16):1903-13.

Comparison of an everolimus-eluting stent and a paclitaxel-eluting stent in patients with coronary artery disease: a randomized trial.

Stone GW, Midei M, Newman W, Sanz M, Hermiller JB, Williams J, Farhat N, Mahaffey KW, Cutlip DE, Fitzgerald PJ, Sood P, Su X, Lansky AJ; SPIRIT III Investigators.

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Comment in:

- JAMA. 2008 Apr 23;299(16):1952-3.

Abstract

CONTEXT: A thin, cobalt-chromium stent eluting the antiproliferative agent everolimus from a nonadhesive, durable fluoropolymer has shown promise in preliminary studies in improving clinical and angiographic outcomes in patients with coronary artery disease. OBJECTIVE: To evaluate the safety and efficacy of an everolimus-eluting stent compared with a widely used paclitaxel-eluting stent. Design, Setting, and PATIENTS: The SPIRIT III trial, a prospective, randomized, single-blind, controlled trial enrolling patients at 65 academic and community-based US institutions between June 22, 2005, and March 15, 2006. Patients were 1002 men and women undergoing percutaneous coronary intervention in lesions 28 mm or less in length and with reference vessel diameter between 2.5 and 3.75 mm. Angiographic follow-up was prespecified at 8 months in 564 patients and completed in 436 patients. Clinical follow-up was performed at 1, 6, 9, and 12 months. INTERVENTIONS: Patients were randomized 2:1 to receive the everolimus-eluting stent (n = 669) or the paclitaxel-eluting stent (n = 333). MAIN OUTCOME MEASURES: The primary end point was noninferiority or superiority of angiographic

in-segment late loss. The major secondary end point was noninferiority assessment of target vessel failure events (cardiac death, myocardial infarction, or target vessel revascularization) at 9 months. An additional secondary end point was evaluation of major adverse cardiac events (cardiac death, myocardial infarction, or target lesion revascularization) at 9 and 12 months. RESULTS: Angiographic in-segment late loss was significantly less in the everolimus-eluting stent group compared with the paclitaxel group (mean, 0.14 [SD, 0.41] mm vs 0.28 [SD, 0.48] mm; difference, -0.14 [95% CI, -0.23 to -0.05]; P < or = .004). The everolimus stent was noninferior to the paclitaxel stent for target vessel failure at 9 months (7.2% vs 9.0%, respectively; difference, -1.9% [95% CI, -5.6% to 1.8%]; relative risk, 0.79 [95% CI, 0.51 to 1.23]; P < .001). The everolimus stent compared with the paclitaxel stent resulted in significant reductions in composite major adverse cardiac events both at 9 months (4.6% vs 8.1%; relative risk, 0.56 [95% CI, 0.34 to 0.94]; P = .03) and at 1 year (6.0% vs 10.3%; relative risk, 0.58 [95% CI, 0.37 to 0.90]; P = .02), due to fewer myocardial infarctions and target lesion revascularization procedures. CONCLUSIONS: In this large-scale, prospective randomized trial, an everolimus-eluting stent compared with a paclitaxel-eluting stent resulted in reduced angiographic late loss, noninferior rates of target vessel failure, and fewer major adverse cardiac events during 1 year of follow-up. TRIAL REGISTRATION: clinicaltrials.gov Identifier: NCT00180479.

PMID: 18430909 [PubMed - indexed for MEDLINE]Free Article

26.

Am Heart J. 2008 Apr;155(4):630-9. Epub 2008 Feb 21.

Comparative safety and efficacy of a sirolimus-eluting versus paclitaxel-eluting stent: a meta-analysis.

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Abstract

BACKGROUND: Drug-eluting stents have emerged as the favored device for percutaneous coronary intervention. It is not clear if there are differences in the currently available drug-eluting stents. We performed a meta-analysis to systematically evaluate currently available data comparing sirolimus-

eluting stents (SESs) with paclitaxel-eluting stents (PESs) in patients with coronary artery disease. METHODS: We searched the MEDLINE, Embase, ISI Web of Knowledge, Current Contents, and International Pharmaceutical Abstracts databases, and the Cochrane Central Register of Controlled Trials, as well as scientific meeting abstracts up to November 30, 2006. All randomized controlled trials comparing SES with PES and providing follow-up data of > or = 6 months were eligible for inclusion in our analysis. RESULTS: Data from 12 trials (number of patients 7455) were pooled. There was no difference in death (summary odds ratio [OR] 0.88, 95% CI 0.61-1.25, P = .46), myocardial infarction (summary OR 0.92, 95% CI, 0.71-1.19, P = .51), or stent thrombosis (summary OR 0.75, 95% CI 0.40-1.40, P = .37) between SES and PES. The use of SES was associated with a significant reduction in angiographic restenosis (summary OR 0.64, 95% CI 0.52-0.78, P < .001), target vessel revascularization (5.66% vs 7.70%, summary OR 0.72, 95% CI 0.59-0.88, P = .002), or target lesion revascularization (summary OR 0.67, 95% CI 0.53-0.84, P = .001). CONCLUSIONS: Patients treated with SES appear to have a significantly lower risk of restenosis and need for target vessel revascularization compared with those treated with PES. There is no significant difference between the 2 stents with respect to mortality, myocardial infarction, or early stent thrombosis.

27.

J Interv Cardiol. 2008 Jun;21(3):225-31. Epub 2008 Mar 13.

Effect of Paclitaxel-eluting versus sirolimus-eluting stents on coronary restenosis in Korean diabetic patients.

Kim MH, Hong SJ, Cha KS, Park HS, Chae SC, Hur SH, Gwon HC, Bae JH, Lim DS.

Department of Cardiology, Dong-A University Hospital, Busan, Korea.

Abstract

BACKGROUND: With the introduction of drug-eluting stents (DES), the angiographic rates of restenosis have reduced dramatically but less prominently in diabetic patients. We compared the effects of sirolimus-eluting stents (SES) versus paclitaxel-eluting stents (PES) on 6-month angiographic and clinical outcomes in Korean diabetic patients. METHOD: Diabetic patients with de novo coronary lesions (169 patients with 190 lesions) were randomly assigned to either SES or PES in six different cardiovascular centers from April 2005 to January 2006. Patients with vessel size >2.0 mm and < or =2

vessel diseases requiring < or =2 DES implantation were included in the study. RESULTS: Baseline clinical and angiographic characteristics were similar between the two groups. At 6-month follow-up, the late lumen loss (0.26 +/- 0.76 in the SES group vs. 0.39 +/- 0.92 mm in the PES group, P = 0.356) and the rate of binary restenosis (2.8%[n = 2] in the SES group vs. 6.9%[n = 5] in the PES group, P = 0.441) showed no significant differences. Rates of death (1.2%[n = 1] in the SES group vs. 1.2%[n = 1] in the PES group, P = 1.000), myocardial infarction (1.2%[n = 1] in the SES group vs. 1.2%[n = 1] in the PES group, P = 1.000), and target lesion revascularization (2.4%[n = 2] in the SES group vs. 4.8%[n = 4] in the PES group, P = 0.443) were similar in both groups during 6 months of follow-up. CONCLUSION: The use of either SES or PES demonstrated similar 6-month angiographic and clinical outcomes in Korean diabetic patients with coronary artery disease.

PMID: 18341520 [PubMed - indexed for MEDLINE]

28.

Eur Heart J. 2008 Mar;29(6):718-25. Epub 2008 Feb 12.

Two-year clinical outcome after implantation of sirolimus-eluting and paclitaxel-eluting stents in diabetic patients.

Billinger M, Beutler J, Taghetchian KR, Remondino A, Wenaweser P, Cook S, Togni M, Seiler C, Stettler C, Eberli FR, Lüscher TF, Wandel S, Jüni P, Meier B, Windecker S.

Department of Cardiology, University Hospital Bern, 3010 Bern, Switzerland.

Abstract

AIMS: Percutaneous coronary intervention (PCI) in diabetic patients is associated with an increased risk of restenosis and major adverse cardiac events (MACE). We assessed the impact of diabetes on long-term outcome after PCI with sirolimus-eluting (SES) and paclitaxel-eluting (PES) stents. METHODS AND RESULTS: In the SIRTAX trial, 1012 patients were randomized to treatment with SES (n = 503) or PES (n = 509). A stratified analysis of outcomes was performed according to the presence or absence of diabetes. Baseline characteristics were well balanced between SES and PES in patients with (N = 201) and without diabetes (N = 811). Clinical outcome was worse in diabetic compared with non-diabetic patients regarding death (9.0% vs. 4.1%, P = 0.004) and MACE (defined as cardiac death, myocardial infarction, or TLR; 19.9% vs. 12.7%, P = 0.007) at 2 years. Among diabetic patients, SES reduced

MACE by 47% (14.8% vs. 25.8%, HR = 0.52, P = 0.05) and TLR by 61% (7.4% vs. 17.2%, HR = 0.39, P = 0.03) compared with PES at 2 years. CONCLUSION: Diabetic patients have worse prognosis than non-diabetic patients undergoing PCI with DES. Among the diabetic patient population of this trial, SES reduce repeat revascularization procedures and MACE more effectively than PES and to a similar degree as in non-diabetic patients.

PMID: 18272504 [PubMed - indexed for MEDLINE]Free Article

- 29.

JAMA. 2008 Jan 30;299(4):409-16.

Comparison of paclitaxel- and sirolimus-eluting stents in everyday clinical practice: the SORT OUT II randomized trial.

Galløe AM, Thuesen L, Kelbaek H, Thayssen P, Rasmussen K, Hansen PR, Bligaard N, Saunamäki K, Junker A, Aarøe J, Abildgaard U, Ravkilde J, Engstrøm T, Jensen JS, Andersen HR, Bøtker HE, Galatius S, Kristensen SD, Madsen JK, Krusell LR, Abildstrøm SZ, Stephansen GB, Lassen JF; SORT OUT II Investigators.

Department of Cardiology, Gentofte University Hospital, Hellerup, Copenhagen, Denmark. anders@galloe.dk

Comment in:

- JAMA. 2008 May 7;299(17):2021-2; author reply 2022.
- JAMA. 2008 Jan 30;299(4):454-5.

Abstract

CONTEXT: Approval of drug-eluting coronary stents was based on results of relatively small trials of selected patients; however, in routine practice, stents are used in a broader spectrum of patients. OBJECTIVE: To compare the first 2 commercially available drug-eluting stents-sirolimus-eluting and paclitaxel-eluting-for prevention of symptom-driven clinical end points, using a study design reflecting everyday clinical practice. DESIGN, SETTING, AND PATIENTS: Randomized, blinded trial conducted August 2004 to January 2006 at 5 university hospitals in Denmark. Patients were 2098 men and women

(mean [SD] age, 63.6 [10.8] years) treated with percutaneous coronary intervention (PCI) and randomized to receive either sirolimus-eluting (n = 1065) or paclitaxel-eluting (n = 1033) stents. Indications for PCI included ST-segment elevation myocardial infarction (STEMI), non-STEMI or unstable angina pectoris, and stable angina. MAIN OUTCOME MEASURES: The primary end point was a composite clinical end point of major adverse cardiac events, defined as either cardiac death, acute myocardial infarction, target lesion revascularization, or target vessel revascularization. Secondary end points included individual components of the composite end point, all-cause mortality, and stent thrombosis. RESULTS: The sirolimus- and the paclitaxel-eluting stent groups did not differ significantly in major adverse cardiac events (98 [9.3%] vs 114 [11.2%]; hazard ratio, 0.83 [95% confidence interval, 0.63-1.08]; P = .16) or in any of the secondary end points. The stent thrombosis rates were 27 (2.5%) and 30 (2.9%) (hazard ratio, 0.87 [95% confidence interval, 0.52-1.46]; P = .60), respectively. CONCLUSION: In this practical randomized trial, there were no significant differences in clinical outcomes between patients receiving sirolimus- and paclitaxel-eluting stents. TRIAL REGISTRATION: clinicaltrials.gov Identifier: NCT00388934.

PMID: 18230778 [PubMed - indexed for MEDLINE]Free Article

30.

Eur Heart J. 2007 Nov;28(22):2720-5. Epub 2007 Oct 7.

Randomized trial of rapamycin- and paclitaxel-eluting stents with identical biodegradable polymeric coating and design.

Wessely R, Kastrati A, Mehilli J, Dibra A, Pache J, Schömig A.

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Abstract

AIMS: This prospective, randomized study sought to directly compare the performance of paclitaxel and rapamycin on an otherwise identical, polymer-coated drug-eluting stent (DES) platform. METHODS AND RESULTS: Stents with identical design and biodegradable polymeric coating that elute either rapamycin or paclitaxel over a 2 months time period were utilized. In this pilot trial that included 91 patients, both stent platforms proved safe with no case of death, Q-wave myocardial infarction or stent

thrombosis within a 9 months follow-up period. Late-lumen loss was markedly greater in the paclitaxel-eluting stent group compared with the rapamycin-eluting stent group (0.96 +/- 0.75 vs. 0.33 +/- 0.46 mm, P < 0.0001). Likewise, the rate of angiographic restenosis was higher in the paclitaxel-eluting stent group compared with the rapamycin-eluting stent group [39.0 vs. 12.2%; relative risk (RR) 3.20 (95% confidence interval, 1.29-7.92), P = 0.005]. Concomitantly, the need for target lesion revascularization was higher in the paclitaxel-eluting stent group compared with the rapamycin-eluting stent group [26.7 vs. 8.7%; RR 3.07 (1.07-8.80), P = 0.02]. CONCLUSION: The results of this clinical trial that is the first to directly compare the performance of paclitaxel and rapamycin on a DES platform otherwise identical in design and polymeric coating imply that rapamycin is more effective for the prevention of coronary restenosis on a DES platform with mid-term drug release and less dependent on release kinetics than paclitaxel. Thus, to ensure efficacy, drug release from a paclitaxel-coating stent platform must be prolonged and well controlled to achieve results that are comparable with the FDA-approved paclitaxel-eluting stent platform.

PMID: 17921531 [PubMed - indexed for MEDLINE]Free Article

31.

Diabetes Care. 2008 Jan;31(1):15-9. Epub 2007 Oct 1.

Head-to-head comparison of sirolimus- and paclitaxel-eluting stent in the same diabetic patient with multiple coronary artery lesions: a prospective, randomized, multicenter study.

Tomai F, Reimers B, De Luca L, Galassi AR, Gaspardone A, Ghini AS, Ferrero V, Favero L, Gioffrè G, Prati F, Tamburino C, Ribichini F.

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Abstract

OBJECTIVE: It is still controversial whether sirolimus-eluting stent (SES) and paclitaxel-eluting stent (PES) are equally effective in patients with diabetes. In these patients, multiple individual variables may be responsible for neointimal hyperplasia, thus making difficult the comparison of the two drug-eluting stents (DES). RESEARCH DESIGN AND METHODS: We designed a prospective, randomized study to

compare the efficacy in prevention of restenosis of SES and PES, both implanted in the same diabetic patient with multiple de novo coronary artery lesions undergoing elective percutaneous coronary intervention. We enrolled 60 patients with diabetes with at least two significant de novo angiographic stenoses in different coronary segments. The primary end point was in-stent late luminal loss (LLL) at 8-month angiographic follow-up. RESULTS: A total of 120 lesions were successfully treated with the randomly assigned DES (SES, n = 60; PES, n = 60). In-stent LLL was lower in the SES than in the PES group (0.26 +/- 0.4 vs. 0.50 +/- 0.6 mm; P = 0.01). Coronary lesions treated with SES presented a reduced in-stent LLL in 40 (68%) patients, while PES resulted in a lower in-stent LLL in 19 (32%) patients (P = 0.0002). At multivariable analysis, the type of DES implanted was the only independent predictor of in-stent LLL (odds ratio 2.3 [95% CI 1.1-5.0]; P = 0.03). CONCLUSIONS: SES directly compared with PES in the same diabetic patient is associated with a decrease in the extent of in-stent LLL at 8 months, suggesting a reduced risk of restenosis.

PMID: 17909090 [PubMed - indexed for MEDLINE]Free Article

32.

J Am Coll Cardiol. 2007 Oct 2;50(14):1373-80. Epub 2007 Aug 21.

A meta-analysis of 16 randomized trials of sirolimus-eluting stents versus paclitaxel-eluting stents in patients with coronary artery disease.

Schömig A, Dibra A, Windecker S, Mehilli J, Suárez de Lezo J, Kaiser C, Park SJ, Goy JJ, Lee JH, Di Lorenzo E, Wu J, Jüni P, Pfisterer ME, Meier B, Kastrati A.

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Comment in:

- J Am Coll Cardiol. 2007 Oct 2;50(14):1381-5.

Abstract

OBJECTIVES: Our purpose was to make a synthesis of the available evidence on the relative efficacy and safety of 2 drug-eluting stents (DES)--sirolimus-eluting stent (SES) and paclitaxel-eluting stent (PES)--in patients with coronary artery disease. BACKGROUND: It is not known whether there are

differences in late outcomes between the 2 most commonly used DES: SES and PES. METHODS: Sixteen randomized trials of SES versus PES with a total number of 8,695 patients were included in this meta-analysis. A full set of individual outcome data from 5,562 patients was also available. Mean follow-up period ranged from 9 to 37 months. The primary efficacy end point was the need for reintervention (target lesion revascularization). The primary safety end point was stent thrombosis. Secondary end points were death and recurrent myocardial infarction (MI). RESULTS: No significant heterogeneity was found across trials. Compared with PES, SES significantly reduced the risk of reintervention (hazard ratio [HR] 0.74; 95% confidence interval [CI] 0.63 to 0.87, $p < 0.001$) and stent thrombosis (HR 0.66; 95% CI 0.46 to 0.94, $p = 0.02$) without significantly impacting on the risk of death (HR 0.92; 95% CI 0.74 to 1.13, $p = 0.43$) or MI (HR 0.84; 95% CI 0.69 to 1.03, $p = 0.10$). CONCLUSIONS: Sirolimus-eluting stents are superior to PES in terms of a significant reduction of the risk of reintervention and stent thrombosis. The risk of death was not significantly different between the 2 DES, but there was a trend toward a higher risk of MI with PES, especially after the first year from the procedure.

PMID: 17903638 [PubMed - indexed for MEDLINE]

33.

Catheter Cardiovasc Interv. 2007 Aug 1;70(2):163-6.

Three-year follow-up of the first prospective randomized comparison between paclitaxel and sirolimus stents: the TAXi-LATE trial.

Berger A, Stauffer JC, Seydoux C, Siegenthaler M, Benoît A, Goy JJ.

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Abstract

GOAL: Analysis of the 3-year outcome of the original population of the TAXi trial which compared the efficacy of the paclitaxel (PES) and the sirolimus (SES) stents in a randomized "real world" investigation. HISTORY: The widespread use of drug-eluting stents strongly modified the world of interventional cardiology. The TAXi trial was a randomized comparison between PES and SES and showed similar efficacy between the two prostheses. Recently, emerging discussions raised questions about potential long-term risk with the use of DES. The present work attempts to describe the long-term outcome of the patients compared during the TAXi trial. METHOD: During April 2003 and January 2004, 202 patients

were prospectively randomly assigned to the PES group (102 patients) and to the SES group (100 patients). The primary aim of the present investigation was the comparison of combined incidence of cardiac death, myocardial infarction, and target lesion revascularization within 36-months. RESULTS: No difference in mortality of all causes was noted in the PES and the SES groups (3% vs. 7%, P=0.98) or in major adverse cardiac event free survival (89% vs. 83%, P=0.28). Four stent thromboses were observed, two in the PES group (205 and 788 days) and two in the SES group (210 and 772 days). CONCLUSION: The long-term outcome analysis of the TAXi trial confirms available published data showing the equivalence of PES and SES on clinical basis. Copyright (c) 2007 Wiley-Liss, Inc.

PMID: 17630653 [PubMed - indexed for MEDLINE]

- 34.

Am Heart J. 2007 Jan;153(1):15.e1-7.

Drug-eluting stents for the treatment of bifurcation lesions: a randomized comparison between paclitaxel and sirolimus stents.

Pan M, Suárez de Lezo J, Medina A, Romero M, Delgado A, Segura J, Ojeda S, Mazuelos F, Hernandez E, Melian F, Pavlovic D, Esteban F, Herrador J.

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Abstract

BACKGROUND: Drug-eluting stents have been shown to reduce restenosis in many types of lesions. The purpose of this article is to assess the efficacy of sirolimus- and paclitaxel-eluting stents in patients with bifurcation lesions. METHODS: Between June 2003 and October 2004, 205 patients were enrolled in a prospective randomized trial; 103 patients were assigned to sirolimus stents and 102 patients to paclitaxel stents. All patients were treated by provisional T-stenting. RESULTS: There were no differences between groups in terms of age, risk factors, clinical condition, location of the bifurcation lesion, or other technical factors. Angiographic data and immediate results were also similar in both groups. Three patients developed inhospital non-Q-wave acute myocardial infarction (2 from the sirolimus group and 1 from the paclitaxel group). Follow-up angiography was obtained in 109 patients (53%). In the sirolimus group, 5 patients developed restenosis (9%): 1 at the main vessel, 2 at the side

branch, and 2 in both branches. In contrast, 16 patients from the paclitaxel group had restenosis (29%): 6 at the main vessel, 5 at the side branch, and 5 in both branches. Target lesion revascularization at 24 +/- 5 months post stenting occurred in 4 patients from the sirolimus group (4%) and in 13 from the paclitaxel group (13%) (P < .05). Late loss at the main vessel in the sirolimus group patients was 0.31 +/- 0.59 versus 0.60 +/- 0.77 mm in patients from the paclitaxel group (P < .05). CONCLUSIONS: Patients with bifurcation lesions treated by sirolimus showed significantly lower rates of late loss, restenosis and target lesion revascularization than patients treated with paclitaxel-eluting stents.

35.

J Am Coll Cardiol. 2006 Dec 19;48(12):2440-7. Epub 2006 Nov 28.

Comparison of zotarolimus-eluting and sirolimus-eluting stents in patients with native coronary artery disease: a randomized controlled trial.

Kandzari DE, Leon MB, Popma JJ, Fitzgerald PJ, O'Shaughnessy C, Ball MW, Turco M, Applegate RJ, Gurbel PA, Midei MG, Badre SS, Mauri L, Thompson KP, LeNarz LA, Kuntz RE; ENDEAVOR III Investigators.

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Abstract

OBJECTIVES: This trial examined the relative clinical efficacy, angiographic outcomes, and safety of zotarolimus-eluting coronary stents (ZES) with a phosphorylcholine polymer versus sirolimus-eluting stents (SES). BACKGROUND: Whether a cobalt-based alloy stent coated with the novel antiproliferative agent, zotarolimus, and a phosphorylcholine polymer may provide similar angiographic and clinical benefit compared with SES is undetermined. METHODS: A prospective, multicenter, 3:1 randomized trial was conducted to evaluate the safety and efficacy of ZES (n = 323) relative to SES (n = 113) in 436 patients undergoing elective percutaneous revascularization of de novo native coronary lesions with reference vessel diameters between 2.5 mm and 3.5 mm and lesion length > or =14 mm and < or =27 mm. The primary end point was 8-month angiographic in-segment late lumen loss. RESULTS: Angiographic in-segment late lumen loss was significantly higher among patients treated with ZES compared with SES (0.34 +/- 0.44 mm vs. 0.13 +/- 0.32 mm, respectively; p < 0.001). In-hospital major adverse cardiac events were significantly lower among patients treated with ZES (0.6% vs. 3.5%, p =

0.04). In-segment binary angiographic restenosis was also higher in the ZES cohort (11.7% vs. 4.3%, p = 0.04). Total (clinically and non-clinically driven) target lesion revascularization rates at 9 months were 9.8% and 3.5% for the ZES and SES groups, respectively (p = 0.04). However, neither clinically driven target lesion revascularization (6.3% zotarolimus vs. 3.5% sirolimus, p = 0.34) nor target vessel failure (12.0% zotarolimus vs. 11.5% sirolimus, p = 1.0) differed significantly. CONCLUSIONS: Compared with SES, treatment with a phosphorylcholine polymer-based ZES is associated with significantly higher late lumen loss and binary restenosis at 8-month angiographic follow-up. (The Endeavor III CR; http://clinicaltrials.gov/ct/show/NCT00265668?order=1?).

PMID: 17174180 [PubMed - indexed for MEDLINE]

36.

Circulation. 2006 Nov 14;114(20):2148-53. Epub 2006 Oct 23.

Sirolimus-eluting stent versus paclitaxel-eluting stent for patients with long coronary artery disease.

Kim YH, Park SW, Lee SW, Park DW, Yun SC, Lee CW, Hong MK, Kim HS, Ko JK, Park JH, Lee JH, Choi SW, Seong IW, Cho YH, Lee NH, Kim JH, Chun KJ, Park SJ; Long-DES-II Study Investigators.

Asan Medical Center, University of Ulsan College of Medicine, Seoul, Korea.

Abstract

BACKGROUND: Outcomes remain relatively unfavorable for stent-based coronary intervention of lesions with long diseased segments. This study compared sirolimus-eluting stents (SES) and paclitaxel-eluting stents (PES) for long coronary lesions. METHODS AND RESULTS: The present randomized, multicenter, prospective study compared the use of long (> or =32 mm) SES with PES in 500 patients with long (> or =25 mm) native coronary lesions. The primary end point of the trial was the rate of binary in-segment restenosis according to follow-up angiography at 6 months. The SES and PES groups had similar baseline characteristics. Lesion length was 33.9+/-11.6 mm in the SES group and 34.5+/-12.6 mm in the PES group (P=0.527). The in-segment binary restenosis rate was significantly lower in the SES group than in the PES group (3.3% versus 14.6%; relative risk 0.23; P<0.001). In-stent late loss of lumen diameter was 0.09+/-0.37 mm in the SES group and 0.45+/-0.55 mm in the PES group (P<0.001). In patients with restenoses, a pattern of focal restenosis was more common in the

SES group than in the PES group (100% versus 53.3%, P=0.031). Consequently, SES patients had a lower rate of target-lesion revascularization at 9 months (2.4% versus 7.2%, P=0.012). The incidence of death (0.8% in SES versus 0% in PES, P=0.499) or myocardial infarction (8.8% in SES versus 10.8% in PES, P=0.452) at 9 months of follow-up was not statistically different between the 2 groups.

CONCLUSIONS: For patients with long native coronary artery disease, SES implantation was associated with a reduced incidence of angiographic restenosis and a reduced need for target-lesion revascularization compared with PES implantation.

PMID: 17060388 [PubMed - indexed for MEDLINE]Free Article

37.

Catheter Cardiovasc Interv. 2006 Jun;67(6):846-51.

"Head-to-head comparison between sirolimus-eluting and paclitaxel-eluting stents in patients with complex coronary artery disease: an intravascular ultrasound study".

Cervinka P, Costa MA, Angiolillo DJ, Spacek R, Bystron M, Kvasnák M, Veselka J, Nanda H, Futamatsu H, Futamatsu K.

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Abstract

BACKGROUND: The aim of this study was to assess neointimal hyperplasia following sirolimus-eluting (SES) and paclitaxel-eluting stents (PES) implantation in a patients with complex coronary disease.

METHOD: Between January to December 2004, 70 patients were enrolled in this study (SES = 37; PES = 33. The primary objective was to assess the efficacy of SES and PES on neointimal proliferation inhibition in patients with complex coronary lesions by volumetric 3D intravascular ultrasound (IVUS) assessment at six-month follow-up. RESULTS: Baseline clinical, demographic or angiographic characteristics were well balanced in both groups. All procedures as well as hospitalisation were uneventful. The percentage of B2/C lesions in our study was > 90% in both groups. The IVUS-assessed in-stent mean neointimal hyperplasia volume was significantly lower in lesions treated with SES compared to PES (4.1 +/- 11 mm3 vs. 17.4 +/- 23 mm3, p < 0.002) at 6 month follow-up. No difference in both MACE (3.0 versus 6.0%, p = NS) and restenosis (5.4 versus 9.1%, p = NS) were found. The in-

segment late loss at six month was 0.26 mm in the SES and 0.48 mm in the PES group (p = NS). CONCLUSIONS: The present study showed reduced neointimal proliferation after sirolimuseluting as compared to paclitaxel-eluting stents in patients with complex coronary artery disease. Both SES and PES were associated with low rate of angiographic restenosis or major adverse cardiovascular events.

38.

Eur Heart J. 2006 Feb;27(3):260-6. Epub 2006 Jan 9.

Randomized trial of paclitaxel- and sirolimus-eluting stents in small coronary vessels.

Mehilli J, Dibra A, Kastrati A, Pache J, Dirschinger J, Schömig A; Intracoronary Drug-Eluting Stenting to Abrogate Restenosis in Small Arteries (ISAR-SMART 3) Study Investigators.

Deutsches Herzzentrum, Technische Universität, Lazarettstr. 36, 80636 Munich, Germany.

Abstract

AIMS: Sirolimus- and paclitaxel-eluting stents effectively reduce restenosis in small coronary vessels. The relative efficacy of these drug-eluting stents in this high-risk subset is not known. METHODS AND RESULTS: A total of 360 patients undergoing percutaneous coronary intervention for de novo lesions in native coronary vessels with a diameter of <2.80 mm received randomly paclitaxel-eluting stents (n=180) or sirolimus-eluting stents (n=180). The primary endpoint was in-stent late luminal loss. Secondary endpoints were angiographic restenosis and need of target lesion revascularization. The study intended to show that the paclitaxel-eluting stent is not inferior to the sirolimus-eluting stent with respect to the primary endpoint. The non-inferiority margin was set at 0.16 mm. Follow-up angiography was performed in 87% of the patients. In-stent late luminal loss in the paclitaxel-eluting stent group was 0.32 mm (upper 95% boundary, 0.42 mm), which was greater than that in the sirolimus-eluting stent group, failing to show the non-inferiority of the paclitaxel-eluting stent to the sirolimus-eluting stent (P>0.99). Angiographic restenosis was found in 19.0% of the lesions in the paclitaxel-eluting stent group and 11.4% of the lesions in the sirolimus-eluting stent group (P=0.047). Target lesion revascularization was performed in 14.7% of the lesions treated with paclitaxel-eluting stents and 6.6% of the lesions treated with sirolimus-eluting stents (P=0.008). CONCLUSION: The paclitaxel-eluting stent is associated

with a greater late luminal loss and is less effective in reducing restenosis in small coronary vessels than the sirolimus-eluting stent.

PMID: 16401670 [PubMed - indexed for MEDLINE]Free Article

39.

Circulation. 2006 Jan 17;113(2):273-9. Epub 2006 Jan 3.

Randomized trial of a nonpolymer-based rapamycin-eluting stent versus a polymer-based paclitaxel-eluting stent for the reduction of late lumen loss.

Mehilli J, Kastrati A, Wessely R, Dibra A, Hausleiter J, Jaschke B, Dirschinger J, Schömig A; Intracoronary Stenting and Angiographic Restenosis--Test Equivalence Between 2 Drug-Eluting Stents (ISAR-TEST) Trial Investigators.

Deutsches Herzzentrum, Technische Universität, Munich, Germany.

Abstract

BACKGROUND: Although drug-eluting stents (DESs) constitute a major achievement in preventing restenosis, concerns remain regarding the increased inflammatory and thrombogenic responses associated with the polymers used. Recently, we showed that a nonpolymer on-site coating with rapamycin not only is feasible and safe but also leads to a dose-dependent reduction in restenosis. METHODS AND RESULTS: To assess whether polymer-free stents coated on-site with 2% rapamycin solution are inferior to polymer-based paclitaxel-eluting stents for the prevention of restenosis, we randomly assigned a total of 450 patients with de novo lesions in native coronary vessels, excluding the left main trunk, to either the polymer-free, rapamycin-coated Yukon DES (rapamycin stent) or the polymer-based, paclitaxel-eluting Taxus stent (paclitaxel stent). The primary end point was in-stent late lumen loss. Secondary end points were angiographic restenosis and target lesion revascularization. The study was designed to test the noninferiority of the rapamycin stent compared with the paclitaxel stent with respect to late lumen loss according to a noninferiority margin of 0.13 mm. Follow-up angiography was completed in 81% of the patients. The mean difference in in-stent late lumen loss between the rapamycin-stent group and the paclitaxel-stent group was 0.002 mm, and the upper limit of the 1-sided 95% confidence interval was 0.10 mm (P=0.02 from test for noninferiority). No significant differences

were observed regarding angiographic restenosis rates (14.2% with the rapamycin stent and 15.5% with the paclitaxel stent) and target lesion revascularization rates due to restenosis (9.3% in both groups). CONCLUSIONS: The polymer-free, rapamycin-coated stent has an antirestenotic effect that is not inferior to that observed with the polymer-based paclitaxel-eluting stent.

40.

Int J Cardiol. 2007 Jan 2;114(1):104-5. Epub 2005 Dec 19.

Direct and indirect comparison meta-analysis demonstrates the superiority of sirolimus- versus paclitaxel-eluting stents across 5854 patients.

Biondi-Zoccai GG, Lotrionte M, Abbate A, Valgimigli M, Testa L, Burzotta F, Crea F, Agostoni P.

Abstract

There is ongoing debate to identify the most effective, safe and cost-beneficial drug-eluting stent, between the two currently approved and used devices, i.e. sirolimus-eluting stents (SES) and paclitaxel-eluting stents (PES). To date, head-to-head comparison studies of SES vs PES have been however limited by relatively small sample sizes and the low number of events typically associated with these highly effective coronary devices. To overcome the drawbacks of single trials, direct and indirect comparison meta-analyses have been designed and conducted to thoroughly compare sirolimus- vs paclitaxel eluting-stents. This article provides results of a pooled analysis of such indirect and direct comparisons, definitively demonstrating across 5854 patients the superiority of SES in comparison to PES (odds ratio 0.62 [95% confidence interval 0.50-0.75], p<0.0001 for binary angiographic restenosis, and odds ratio 0.66 [0.52-0.84], p=0.0008 for target lesion revascularization). Indeed, such combination of direct and indirect comparisons should also be envisaged to soundly and timely appraise the next generation of drug-eluting stents.

PMID: 16360225 [PubMed - indexed for MEDLINE]

- 41.

JAMA. 2005 Aug 17;294(7):819-25.

Sirolimus-eluting stents vs paclitaxel-eluting stents in patients with coronary artery disease: meta-analysis of randomized trials.

Kastrati A, Dibra A, Eberle S, Mehilli J, Suárez de Lezo J, Goy JJ, Ulm K, Schömig A.

Deutsches Herzzentrum, Technische Universität, Munich, Germany. kastrati@dhm.mhn.de

Abstract

CONTEXT: Placement of sirolimus-eluting stents or paclitaxel-eluting stents has emerged as the predominant percutaneous treatment strategy in patients with coronary artery disease (CAD). Whether there are any differences in efficacy and safety between these 2 drug-eluting stents is unclear. OBJECTIVE: To compare outcomes of sirolimus-eluting and paclitaxel-eluting coronary stents on the basis of data generated by randomized head-to-head clinical trials. DATA SOURCES: PubMed and the Cochrane Central Register of Controlled Trials, conference proceedings from major cardiology meetings, and Internet-based sources of information on clinical trials in cardiology from January 2003 to April 2005. STUDY SELECTION: Randomized trials comparing the sirolimus-eluting stent with the paclitaxel-eluting stent in patients with CAD reporting the outcomes of interest (target lesion revascularization, angiographic restenosis, stent thrombosis, myocardial infarction [MI], death, and the composite of death or MI) during a follow-up of at least 6 months. DATA EXTRACTION: Two reviewers independently identified studies and abstracted data on sample size, baseline characteristics, and outcomes of interest. DATA SYNTHESIS: Six trials, including 3669 patients, met the selection criteria. No significant heterogeneity was found across trials. Target lesion revascularization, the primary outcome of interest, was less frequently performed in patients who were treated with the sirolimus-eluting stent (5.1%) vs the paclitaxel-eluting stent (7.8%) (odds ratio [OR], 0.64; 95% confidence interval [CI], 0.49-0.84; P = .001). Similarly, angiographic restenosis was less frequently observed among patients assigned to the sirolimus-eluting stent (9.3%) vs the paclitaxel-eluting stent (13.1%) (OR, 0.68; 95% CI, 0.55-0.86; P = .001). Event rates for sirolimus-eluting vs paclitaxel-eluting stents were 0.9% and 1.1%, respectively, for stent thrombosis (P = .62); 1.4% and 1.6%, respectively, for death (P = .56); and 4.9% and 5.8%, respectively, for the composite of death or MI (P = .23). CONCLUSIONS: Patients receiving sirolimus-eluting stents had a significantly lower risk of restenosis and target vessel revascularization compared with those receiving paclitaxel-eluting stents. Rates of death, death or MI, and stent thrombosis were similar.

N Engl J Med. 2005 Aug 18;353(7):663-70. Epub 2005 Aug 16.

Paclitaxel-eluting or sirolimus-eluting stents to prevent restenosis in diabetic patients.

Dibra A, Kastrati A, Mehilli J, Pache J, Schühlen H, von Beckerath N, Ulm K, Wessely R, Dirschinger J, Schömig A; ISAR-DIABETES Study Investigators.

Deutsches Herzzentrum, Technische Universität, Munich, Germany.

Comment in:

- N Engl J Med. 2005 Aug 18;353(7):724-7.
- N Engl J Med. 2005 Dec 1;353(22):2404-8; author reply 2404-8.
- N Engl J Med. 2005 Dec 1;353(22):2404-8; author reply 2404-8.

Abstract

BACKGROUND: Drug-eluting stents are highly effective in reducing the rate of in-stent restenosis. It is not known whether there are differences in the effectiveness of currently approved drug-eluting stents in the high-risk subgroup of patients with diabetes mellitus. METHODS: We enrolled 250 patients with diabetes and coronary artery disease: 125 were randomly assigned to receive paclitaxel-eluting stents, and 125 to receive sirolimus-eluting stents. The primary end point was in-segment late luminal loss. Secondary end points were angiographic restenosis (defined as in-segment stenosis of at least 50 percent at follow-up angiography) and the need for revascularization of the target lesion during a nine-month follow-up period. The study was designed to show noninferiority of the paclitaxel stent as compared with the sirolimus stent, defined as a difference in the extent of in-segment late luminal loss of no more than 0.16 mm. RESULTS: The extent of in-segment late luminal loss was 0.24 mm (95 percent confidence interval, 0.09 to 0.39) greater in the paclitaxel-stent group than in the sirolimus-stent group (P=0.002). In-segment restenosis was identified on follow-up angiography in 16.5 percent of the patients in the paclitaxel-stent group and 6.9 percent of the patients in the sirolimus-stent group (P=0.03). Target-lesion revascularization was performed in 12.0 percent of the patients in the paclitaxel-stent group and 6.4 percent of the patients in the sirolimus-stent group (P=0.13). CONCLUSIONS: In patients with diabetes mellitus and coronary artery disease, use of the sirolimus-eluting stent is associated with a

decrease in the extent of late luminal loss, as compared with use of the paclitaxel-eluting stent, suggesting a reduced risk of restenosis. Copyright 2005 Massachusetts Medical Society.

PMID: 16105990 [PubMed - indexed for MEDLINE]Free Article

43.

J Am Coll Cardiol. 2008 Apr 22;51(16):1543-52.

A novel bioresorbable polymer paclitaxel-eluting stent for the treatment of single and multivessel coronary disease: primary results of the COSTAR (Cobalt Chromium Stent With Antiproliferative for Restenosis) II study.

Krucoff MW, Kereiakes DJ, Petersen JL, Mehran R, Hasselblad V, Lansky AJ, Fitzgerald PJ, Garg J, Turco MA, Simonton CA 3rd, Verheye S, Dubois CL, Gammon R, Batchelor WB, O'Shaughnessy CD, Hermiller JB Jr, Schofer J, Buchbinder M, Wijns W; COSTAR II Investigators Group.

Duke Clinical Research Institute, Duke University Medical Center, Durham, North Carolina 27705, USA. kruco001@mc.duke.edu

Abstract

OBJECTIVES: The aim was to compare safety and effectiveness of the CoStar drug-eluting stent (DES) (Conor MedSystems, Menlo Park, California) with those of the Taxus DES (Boston Scientific, Maple Grove, Minnesota) in de novo single- and multivessel percutaneous coronary intervention (PCI). BACKGROUND: Paclitaxel elution from a stent coated with biostable polymer (Taxus) reduces restenosis after PCI. The CoStar DES is a novel stent with laser-cut reservoirs containing bioresorbable polymer loaded to elute 10 microg paclitaxel/30 days. METHODS: Patients undergoing PCI for a single target lesion per vessel in up to 3 native epicardial vessels were randomly assigned 3:2 to CoStar or Taxus. Primary end point was 8-month major adverse cardiac events (MACE), defined as adjudicated death, myocardial infarction (MI), or clinically driven target vessel revascularization (TVR). Protocol-specified 9-month angiographic follow-up included 457 vessels in 286 patients. RESULTS: Of the 1,700 patients enrolled, 1,675 (98.5%) were evaluable (CoStar = 989; Taxus = 686), including 1,330 (79%) single-vessel and 345 (21%) multivessel PCI. The MACE rate at 8 months was 11.0% for CoStar versus

6.9% for Taxus (p < 0.005), including adjudicated death (0.5% vs. 0.7%, respectively), MI (3.4% vs. 2.4%, respectively), and TVR (8.1% vs. 4.3%, respectively). Per-vessel 9-month in-segment late loss was 0.49 mm with CoStar and 0.18 mm with Taxus (p < 0.0001). Findings were consistent across pre-specified subgroups. CONCLUSIONS: The CoStar DES is not noninferior to the Taxus DES based on per-patient clinical and per-vessel angiographic analyses. The relative benefit of Taxus is primarily attributable to reduction in TVR. Follow-up to 9 months showed no apparent difference in death, MI, or stent thrombosis rates.

PMID: 18420096 [PubMed - indexed for MEDLINE]

44.

JACC Cardiovasc Interv. 2009 Aug;2(8):779-84.

Intravascular ultrasound results from the ENDEAVOR IV trial: randomized comparison between zotarolimus- and paclitaxel-eluting stents in patients with coronary artery disease.

Waseda K, Miyazawa A, Ako J, Hasegawa T, Tsujino I, Sakurai R, Yock PG, Honda Y, Kandzari DE, Leon MB, Fitzgerald PJ; ENDEAVOR IV Trial Investigators.

Center for Cardiovascular Technology, Division of Cardiovascular Medicine, Stanford University, Stanford, California 94305, USA.

Abstract

OBJECTIVES: The aim of this study was to compare the vessel response between zotarolimus-eluting stents (ZES) and paclitaxel-eluting stents (PES) using intravascular ultrasound. BACKGROUND: The ENDEAVOR IV (Randomized Comparison of Zotarolimus- and Paclitaxel-Eluting Stents in Patients With Coronary Artery Disease) trial was a randomized controlled study of zotarolimus-eluting, phosphorylcholine-coated, cobalt-alloy stents for the treatment of de novo coronary lesions compared with using PES for the same treatment. METHODS: Data were obtained from patients with serial (baseline and 8-months follow-up) intravascular ultrasound analysis available (n = 198). Volumetric

analysis was performed for vessel, lumen, plaque, stent, and neointima. Cross-sectional narrowing (given as percentage) was defined as neointimal area divided by stent area. Neointima-free frame ratio was calculated as the number of frames without intravascular ultrasound-detectable neointima divided by the total number of frames within the stent. Subsegment analysis was performed at every matched 1-mm subsegment throughout the stent. RESULTS: At follow-up, the ZES group showed significantly greater percentage of neointimal obstruction (16.6 +/- 12.0% vs. 9.9 +/- 8.9%, $p < 0.01$) and maximum cross-sectional narrowing (31.8 +/- 16.1% vs. 25.2 +/- 14.9%, $p < 0.01$) with smaller minimum lumen area than the PES group did. However, the incidence of maximum cross-sectional narrowing >50% was similar in the 2 groups. Neointima-free frame ratio was significantly lower in the ZES group. In overall analysis, whereas the PES group showed positive remodeling during follow-up (13.7 +/- 4.2 mm(3)/mm to 14.3 +/- 4.3 mm(3)/mm), the ZES group showed no significant difference (12.7 +/- 3.6 mm(3)/mm to 12.9 +/- 3.5 mm(3)/mm). In subsegment analysis, significant focal positive vessel remodeling was observed in 5% of ZES and 25% of PES cases ($p < 0.05$). CONCLUSIONS: There were different global and focal vessel responses for ZES and PES. Both drug-eluting stents showed a similar incidence of lesions with severe narrowing despite ZES having a moderate increase in neointimal hyperplasia compared with neointimal hyperplasia in PES. There was a relatively lower neointima-free frame ratio in ZES, suggesting a greater extent of neointimal coverage. (The ENDEAVOR IV Clinical Trial: A Trial of a Coronary Stent System in Coronary Artery Lesions; NCT00217269).

APPENDIX 1: Τεχνικά χαρακτηριστικά των DES stents.

(Από την ηλεκτρονική δημοσίευση του ιατρικού περιοδικού Circulation στην διεύθυνση http://circ.ahajournals.org/cgi/content/full/116/3/316/FIG3184697)

Status of current and investigational devices

Manufacturer	Name	Drug	Stent material	Polymer	Status
Cordis/J&J	Cypher Select	Sirolimus	Stainless steel	Durable	FDA/CE Mark
Boston Scientific	Taxus Liberté	Paclitaxel	Stainless steel	Durable	FDA/CE Mark
Medtronic	Endeavor	Zotarolimus	Cobalt chromium	Durable	CE Mark
Abbott	ZoMaxx	Zotarolimus	Tantalum/stainless steel	Durable	trial
Abbott	Xience V	Everolimus	Cobalt chromium	Durable	CE Mark
Biosensors	BioMatrix	Biolimus-A9	Stainless steel	Bioabsorbable	CE Filed
Conor	CoStar	Paclitaxel	Cobalt chromium	Bioabsorbable	CE Mark
Sahajanand	Supralimus	Sirolimus	Stainless steel	Bioabsorbable	CE Mark
Sahajanand	Infinnium	Paclitaxel	Stainless steel	Bioabsorbable	CE Mark
Terumo	Nobori	Biolimus-A9	Stainless steel	Bioabsorbable	trial
Sorin	Janus	Tacrolimus	Stainless steel	None	CE Mark
Orbus Neich	Genous	EPC capture	Stainless steel	Durable	CE Mark
Biotronik	?	AVT-03	Absorbable metal (Mg)	-	trial
Abbott	-	Everolimus	Biodegradable	-	trial

Figure 3. CE or FDA approval of current and investigational devices.

APPENDIX 2: Μελέτες που ΔΕΝ εκπληρούν τα κριτήρια επιλογής της παρούσης βιβλιογραφικής έρευνας (105 συνολικά).

1.Ann Intern Med. 2010 Mar 16;152(6):370-9.

Meta-analysis: effects of percutaneous coronary intervention versus medical therapy on angina relief.

Wijeysundera HC, Nallamothu BK, Krumholz HM, Tu JV, Ko DT.

Sunnybrook Health Sciences Centre, University of Toronto, Toronto, Ontario, Canada.

Abstract

BACKGROUND: Several meta-analyses have evaluated the efficacy of percutaneous coronary intervention (PCI) compared with medical therapy, but none has focused on angina relief. PURPOSE: To summarize the evidence on the degree of angina relief from PCI compared with medical therapy in patients with stable coronary artery disease. DATA SOURCES: The Cochrane Library (1993 to June 2009), EMBASE (1980 to June 2009), and MEDLINE (1950 to June 2009), with no language restrictions. STUDY SELECTION: Two independent reviewers screened citations to identify randomized, controlled trials of PCI versus medical therapy in patients with stable coronary artery disease. DATA EXTRACTION: Two independent reviewers abstracted data on patient characteristics, study conduct, and outcomes. A random-effects model was used to combine data on freedom from angina and to perform stratified analyses based on duration of follow-up, inclusion of patients with recent myocardial infarction, coronary stent utilization, recruitment period, and utilization of evidence-based medications. DATA SYNTHESIS: A total of 14 trials, enrolling 7818 patients, met the inclusion criteria. Although PCI was associated with an overall benefit on angina relief (odds ratio, 1.69 [95% CI, 1.24 to 2.30]), important heterogeneity across trials was observed. The incremental benefit of PCI observed in older trials (odds ratio, 3.38 [CI, 1.89 to 6.04]) was substantially less and possibly absent in recent trials (odds ratio, 1.13 [CI, 0.76 to 1.68]). An inverse relationship between use of evidence-based therapies and the incremental benefit of PCI was observed. LIMITATIONS: Information about the long-term use of medication was incomplete in most trials. Few trials used drug-eluting stents. Meta-regression analyses used aggregated study-level data from few trials. CONCLUSION: Percutaneous coronary intervention was associated with greater freedom from angina compared with medical therapy,

but this benefit was largely attenuated in contemporary studies. This observation may be related to greater use of evidence-based medications in contemporary trials. PRIMARY FUNDING SOURCE: Canadian Institutes of Health Research.

PMID: 20231568 [PubMed - indexed for MEDLINE]

2

N Engl J Med. 2010 Apr 15;362(15):1374-82. Epub 2010 Mar 15.

Duration of dual antiplatelet therapy after implantation of drug-eluting stents.

Park SJ, Park DW, Kim YH, Kang SJ, Lee SW, Lee CW, Han KH, Park SW, Yun SC, Lee SG, Rha SW, Seong IW, Jeong MH, Hur SH, Lee NH, Yoon J, Yang JY, Lee BK, Choi YJ, Chung WS, Lim DS, Cheong SS, Kim KS, Chae JK, Nah DY, Jeon DS, Seung KB, Jang JS, Park HS, Lee K.

Department of Cardiology, Center for Medical Research and Information, University of Ulsan College of Medicine, Seoul, South Korea.

Comment in:

- N Engl J Med. 2010 Apr 15;362(15):1441-3.

Abstract

BACKGROUND: The potential benefits and risks of the use of dual antiplatelet therapy beyond a 12-month period in patients receiving drug-eluting stents have not been clearly established. METHODS: In two trials, we randomly assigned a total of 2701 patients who had received drug-eluting stents and had been free of major adverse cardiac or cerebrovascular events and major bleeding for a period of at least 12 months to receive clopidogrel plus aspirin or aspirin alone. The primary end point was a composite of myocardial infarction or death from cardiac causes. Data from the two trials were merged for analysis. RESULTS: The median duration of follow-up was 19.2 months. The cumulative risk of the primary outcome at 2 years was 1.8% with dual antiplatelet therapy, as compared with 1.2% with aspirin monotherapy (hazard ratio, 1.65; 95% confidence interval [CI], 0.80 to 3.36; P=0.17). The individual risks of myocardial infarction, stroke, stent thrombosis, need for repeat revascularization, major bleeding, and death from any cause did not differ significantly between the two groups. However, in the

dual-therapy group as compared with the aspirin-alone group, there was a nonsignificant increase in the composite risk of myocardial infarction, stroke, or death from any cause (hazard ratio, 1.73; 95% CI, 0.99 to 3.00; P=0.051) and in the composite risk of myocardial infarction, stroke, or death from cardiac causes (hazard ratio, 1.84; 95% CI, 0.99 to 3.45; P=0.06). CONCLUSIONS: The use of dual antiplatelet therapy for a period longer than 12 months in patients who had received drug-eluting stents was not significantly more effective than aspirin monotherapy in reducing the rate of myocardial infarction or death from cardiac causes. These findings should be confirmed or refuted through larger, randomized clinical trials with longer-term follow-up. (ClinicalTrials.gov numbers, NCT00484926 and NCT00590174.)

PMID: 20231231 [PubMed - indexed for MEDLINE]

3

J Am Coll Cardiol. 2010 Mar 2;55(9):867-71.

Increased rate of stent thrombosis and target lesion revascularization after filter protection in primary percutaneous coronary intervention for ST-segment elevation myocardial infarction: 15-month follow-up of the DEDICATION (Drug Elution and Distal Protection in ST Elevation Myocardial Infarction) trial.

Kaltoft A, Kelbaek H, Kløvgaard L, Terkelsen CJ, Clemmensen P, Helqvist S, Lassen JF, Thuesen L.

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Abstract

OBJECTIVES: The purpose of this study was to evaluate the long-term effects of distal protection during percutaneous coronary intervention (PCI) for ST-segment elevation myocardial infarction (STEMI). BACKGROUND: The use of distal filter protection during primary PCI increases procedure complexity and may influence lesion treatment and stent implantation. METHODS: The STEMI patients were assigned to distal protection (DP) (n = 312) or conventional treatment (CT) (n = 314). Clinical follow-up was performed after 1, 6, and 15 months, and angiographic follow-up after 8 months. All target lesion revascularizations (TLRs) were clinically driven. We report the pre-specified end points of stent thrombosis according to the criteria of the Academic Research Consortium, TLR, and reinfarction after

15 months. RESULTS: The total number of stent thrombosis was 11 in the DP group and 4 in the CT group (p = 0.06). The rate of definite stent thrombosis was significantly increased in the DP group as compared with the CT group, with 9 cases versus 1 (p = 0.01). Clinically driven TLRs (31 patients vs. 18 patients, p = 0.05) and clinically driven target vessel revascularizations (37 patients vs. 22 patients, p = 0.04) were more frequent in the DP group. CONCLUSIONS: In primary PCI for STEMI, the routine use of DP increased the incidence of stent thrombosis and clinically driven target lesion/vessel revascularization during 15 months of follow-up. (Drug Elution and Distal Protection in ST Elevation Myocardial Infarction Trial [DEDICATION]; NCT00192868).

PMID: 20185036 [PubMed - indexed for MEDLINE]

- 4

Am J Cardiol. 2010 Feb 15;105(4):475-9. Epub 2010 Jan 5.

The impact of body mass index on the one year outcomes of patients treated by percutaneous coronary intervention with Biolimus- and Sirolimus-eluting stents (from the LEADERS Trial).

Sarno G, Garg S, Onuma Y, Buszman P, Linke A, Ischinger T, Klauss V, Eberli F, Corti R, Wijns W, Morice MC, di Mario C, van Geuns RJ, Eerdmans P, Garcia-Garcia HM, van Es GA, Goedhart D, de Vries T, Jüni P, Meier B, Windecker S, Serruys P.

Department of Interventional Cardiology, Erasmus Medical Center, Rotterdam, The Netherlands.

Abstract

The aim of this analysis was to assess the effect of body mass index (BMI) on 1-year outcomes in patients enrolled in a contemporary percutaneous coronary intervention trial comparing a sirolimus-eluting stent with a durable polymer to a biolimus-eluting stent with a biodegradable polymer. A total of 1,707 patients who underwent percutaneous coronary intervention were randomized to treatment with either biolimus-eluting stents (n = 857) or sirolimus-eluting stents (n = 850). Patients were assigned to 1 of 3 groups according to BMI: normal (<25 kg/m(2)), overweight (25 to 30 kg/m(2)), or obese (>30 kg/m(2)). At 1 year, the incidence of the composite of cardiac death, myocardial infarction, and clinically justified target vessel revascularization was assessed. In addition, rates of clinically justified target lesion

revascularization and stent thrombosis were assessed. Cox proportional-hazards analysis, adjusted for clinical differences, was used to develop models for 1-year mortality. Forty-five percent of the patients (n = 770) were overweight, 26% (n = 434) were obese, and 29% (n = 497) had normal BMIs. At 1-year follow-up, the cumulative rate of cardiac death, myocardial infarction, and clinically justified target vessel revascularization was significantly higher in the obese group (8.7% in normal-weight, 11.3% in overweight, and 14.5% in obese patients, p = 0.01). BMI (hazard ratio 1.47, 95% confidence interval 1.02 to 2.14, p = 0.04) was an independent predictor of stent thrombosis. Stent type had no impact on the composite of cardiac death, myocardial infarction, and clinically justified target vessel revascularization at 1 year in the 3 BMI groups (hazard ratio 1.08, 95% confidence interval 0.63 to 1.83, p = 0.73). In conclusion, BMI was an independent predictor of major adverse cardiac events at 1-year clinical follow-up. The higher incidence of stent thrombosis in the obese group may suggest the need for a weight-adjusted dose of clopidogrel.

PMID: 20152241 [PubMed - indexed for MEDLINE]

5

Am J Cardiol. 2010 Jan 15;105(2):168-73. Epub 2009 Dec 3.

Comparison of Triple antiplatelet therapy and dual antiplatelet therapy in patients at high risk of restenosis after drug-eluting stent implantation (from the DECLARE-DIABETES and -LONG Trials).

Lee SW, Chun KJ, Park SW, Kim HS, Kim YH, Yun SC, Kim WJ, Lee JY, Park DW, Lee CW, Hong MK, Rhee KS, Chae JK, Ko JK, Park JH, Lee JH, Choi SW, Jeong JO, Seong IW, Jon S, Cho YH, Lee NH, Kim JH, Park SJ.

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Abstract

Although cilostazol has decreased restenosis and target lesion revascularization (TLR) after drug-eluting stent implantation, it is not known if this effect is durable at 2 years. We analyzed 2 randomized studies (Drug-Eluting stenting followed by Cilostazol treatment reduces LAte REstenosis in patients with DIABETES mellitus and Drug-Eluting Stenting Followed by Cilostazol treatment reduces LAte REstenosis in patients with LONG native coronary lesions trials) in which 900 patients were randomly

assigned to triple antiplatelet therapy (aspirin, clopidogrel, and cilostazol; triple group, n = 450) and dual antiplatelet therapy (aspirin and clopidogrel; standard group, n = 450) for 6 months in patients with diabetes or long lesions receiving drug-eluting stents. We evaluated 2-year major adverse cardiac events (MACEs) including death, myocardial infarction (MI), and TLR. Nine-month TLRs and MACEs were significantly decreased in the triple versus standard group. At 2 years, the triple group sowed significantly decreased TLRs (4.2% vs 9.1%, hazard ratio 0.45, 95% confidence interval 0.26 to 0.78, p = 0.004) and MACEs (5.6% vs 10.4%, hazard ratio 0.52, 95% confidence interval 0.32 to 0.84, p = 0.008) compared to the standard group with no differences in death and MI. In subgroup analysis, triple antiplatelet therapy decrease of 2-year TLR was favorable in all subgroups, especially in patients with paclitaxel-eluting stents, diabetes mellitus, small vessels, long lesions, and left anterior descending coronary artery lesions. In conclusion, compared to the standard group, initial benefit in decreases of 9-month TLRs and MACEs in the triple group was sustained at 2 years with no differences in death or MI. Triple antiplatelet therapy decrease of 2-year TLR was favorable in all subgroups, especially in patients with high-risk profiles.

PMID: 20102913 [PubMed - indexed for MEDLINE]


6

J Am Coll Cardiol. 2010 Mar 16;55(11):1067-75. Epub 2010 Jan 14.

Diabetic and nondiabetic patients with left main and/or 3-vessel coronary artery disease: comparison of outcomes with cardiac surgery and paclitaxel-eluting stents.

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Comment in:

- J Am Coll Cardiol. 2010 Mar 16;55(11):1076-9.

Abstract

OBJECTIVES: This study was designed to compare contemporary surgical revascularization (coronary artery bypass graft surgery [CABG]) versus TAXUS Express (Boston Scientific, Natick, Massachusetts) paclitaxel-eluting stents (PES) in diabetic and nondiabetic patients with left main and/or 3-vessel disease. BACKGROUND: Although the prevalence of diabetes mellitus is increasing, the optimal coronary revascularization strategy in diabetic patients with complex multivessel disease remains controversial. METHODS: The SYNTAX (SYNergy between percutaneous coronary intervention with TAXus and cardiac surgery) study randomly assigned 1,800 patients (452 with medically treated diabetes) to receive PES or CABG. RESULTS: The overall 1-year major adverse cardiac and cerebrovascular event rate was higher among diabetic patients treated with PES compared with CABG, but the revascularization method did not impact the death/stroke/myocardial infarction rate for nondiabetic patients (6.8% CABG vs. 6.8% PES, p = 0.97) or for diabetic patients (10.3% CABG vs. 10.1% PES, p = 0.96). The presence of diabetes was associated with significantly increased mortality after either revascularization treatment. The incidence of stroke was higher among nondiabetic patients after CABG (2.2% vs. PES 0.5%, p = 0.006). Compared with CABG, mortality was higher after PES use for diabetic patients with highly complex lesions (4.1% vs. 13.5%, p = 0.04). Revascularization with PES resulted in higher repeat revascularization for nondiabetic patients (5.7% vs. 11.1%, p < 0.001) and diabetic patients (6.4% vs. 20.3%, p < 0.001). CONCLUSIONS: Subgroup analyses suggest that the 1-year major adverse cardiac and cerebrovascular event rate is higher among diabetic patients with left main and/or 3-vessel disease treated with PES compared with CABG, driven by an increase in repeat revascularization. However, the composite safety end point (death/stroke/myocardial infarction) is comparable between the 2 treatment options for diabetic and nondiabetic patients. Although further study is needed, these exploratory results may extend the evidence for PES use in selected patients with less complex left main and/or 3-vessel lesions. (SYNergy Between PCI With TAXus and Cardiac Surgery [SYNTAX]; NCT00114972).

PMID: 20079596 [PubMed - indexed for MEDLINE]

7.

Circ Cardiovasc Interv. 2009 Dec;2(6):535-42. Epub 2009 Nov 10.

Interventional therapy of bifurcation lesions: a TIMI flow-guided concept to treat side branches in bifurcation lesions--a prospective

randomized clinical study (Thueringer bifurcation study, THUEBIS study as pilot trial).

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Comment in:

- Circ Cardiovasc Interv. 2010 Apr;3(2):e2; author reply e3.

Abstract

BACKGROUND: Treatment of bifurcations is a complex problem. The clinical value of treating side branches is an unsolved problem in the field of interventional cardiology. METHODS AND RESULTS: We initiated a prospective randomized controlled trial. One hundred and ten patients with bifurcations were randomly assigned to 2 arms: Stenting of the main branch (MB, Taxus-stent, paclitaxel-eluting stents) and mandatory side branch (SB) percutaneous coronary intervention (PCI; kissing balloons) with provisional SB stenting (therapy A), or stenting of the MB (paclitaxel-eluting stents) with provisional SB-PCI only when the SB had a thrombolysis in myocardial infarction flow <2 (therapy B). The primary end point was target lesion revascularization. The mean ages were 66.8 years (A) versus 65.1 years (B, P=0.4), 71.4% (A) versus 77.8% were men (P=0.4), patients with diabetes were present in 25.0% versus 25.9% (P=0.9). The MB was left anterior descending artery in 80.4% versus 81.5% (A versus B, P=0.9). The SB-PCI and kissing balloon-PCI were performed according to the study protocol in 82.1%/73.2% versus 16.7%/13.0% (P<0.05 for both), while changing of the intended therapy was necessary in 17.9% versus 16.7% (A versus B, P=0.9). A final thrombolysis in myocardial infarction flow 3 (MB) was reached in all patients (groups A and B), final thrombolysis in myocardial infarction flow 3 (SB) was observed in 96.4% versus 88.9% (A versus B, P=0.3). Radiation time (min) and contrast medium (mL) were 14.2/210 (group A) versus 7.8/151.6 (group B; P for both <0.05). Six month - follow up: major adverse cardiac events was 23.2% (A) versus 24.1% (B, P=0.9), target lesion revascularization was 17.9% (A) versus 14.8% (B, P=0.7), and late lumen loss (MB) was 0.2 mm (A) versus 0.3 mm (B, P=0.5). In group B, no PCI of the SB was done during follow up. CONCLUSIONS: A simple strategy using paclitaxel-eluting stents with only provisional SB-PCI may be of equal value to a

more complex strategy with mandatory SB-PCI. Clinical Trial Registration- URL: http://www.controlled.trials.com. Unique identifier: ISRCTN22637771.

PMID: 20031771 [PubMed - indexed for MEDLINE]

8.

Circ Cardiovasc Interv. 2009 Feb;2(1):27-34. Epub 2009 Feb 10.

Randomized comparison of coronary bifurcation stenting with the crush versus the culotte technique using sirolimus eluting stents: the Nordic stent technique study.

Erglis A, Kumsars I, Niemelä M, Kervinen K, Maeng M, Lassen JF, Gunnes P, Stavnes S, Jensen JS, Galløe A, Narbute I, Sondore D, Mäkikallio T, Ylitalo K, Christiansen EH, Ravkilde J, Steigen TK, Mannsverk J, Thayssen P, Hansen KN, Syvänne M, Helqvist S, Kjell N, Wiseth R, Aarøe J, Puhakka M, Thuesen L; Nordic PCI Study Group.

Collaborators (48)
Thuesen L, Lassen JF, Aarøe J, Thayssen P, Helqvist S, Skov Jensen J, Galløe A, James S, Sjögren I, Steigen T, Mannsverk J, Meyerdierks O, Gunnes P, Rotevatn S, Wiseth R, Nikus K, Vikman S, Hartikainen J, Niemela M, Kervinen K, Virtanen K, Airaksinen J, Ylitalo A, Erglis A, Kumsars I, Maeng M, Hoejdahl H, Narbute I, Thuesen L, Skov Jensen J, Aarøe J, Helqvist S, Thayssen P, Steigen T, Gunnes P, Wiseth R, Niemela M, Vikman S, Virtanen K, Puhakka M, Erglis A, Rask Hansen H, Bargsteen H, Frydensberg D, Esbjerg M, Spange Mortensen L, Thygesen K, Nikus K.

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Abstract

BACKGROUND: In a number of coronary bifurcation lesions, both the main vessel and the side branch need stent coverage. Using sirolimus eluting stents, we compared 2 dedicated bifurcation stent techniques, the crush and the culotte techniques in a randomized trial with separate clinical and angiographic end-points. METHODS AND RESULTS: A total of 424 patients with a bifurcation lesion were randomized to crush (n=209) and culotte (n=215) stenting. The primary end point was major adverse cardiac events; cardiac death, myocardial infarction, target vessel revascularization, or stent thrombosis after 6 months. At 6 months there were no significant differences in major adverse cardiac event rates between the groups; crush 4.3%, culotte 3.7% (P=0.87). Procedure and fluoroscopy times and contrast volumes were similar in the 2 groups. The rates of procedure-related increase in

biomarkers of myocardial injury were 15.5% in crush versus 8.8% in culotte group (P=0.08). A total of 324 patients had a quantitative coronary assessment at the index procedure and after 8 months. The angiographic end-points of in-segment and in-stent restenosis of main vessel and/or side branch after 8 months were found in 12.1% versus 6.6% (P=0.10) and in 10.5% versus 4.5% (P=0.046) in the crush and culotte groups, respectively. CONCLUSIONS: Both the crush and the culotte bifurcation stenting techniques were associated with similar and excellent clinical and angiographic results. Angiographically, there was a trend toward less in-segment restenosis and significantly reduced in-stent restenosis following culotte stenting.

PMID: 20031690 [PubMed - indexed for MEDLINE]Free Article

9.

J Cardiovasc Med (Hagerstown). 2010 Feb;11(2):103-10.

True coronary bifurcation lesions: meta-analysis and review of literature.

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Abstract

AIM: Percutaneous intervention of true coronary bifurcation lesions is challenging. Based on the results of randomized trials and registry data, the approach of stenting of main vessel only with balloon dilatation of the side branch has become the default approach for false bifurcation lesions except when a complication occurs or in cases of suboptimal result. However, the optimal stenting strategy for true coronary bifurcation lesions - to stent or not to stent the side branch - is still a matter of debate. The purpose of this study was, therefore, to compare the clinical and angiographic outcomes of the double stent technique (stenting of the main branch and side branch) over the single stent technique (stenting of main vessel only with balloon dilatation of the side branch) for treatment of true coronary bifurcation lesions, with drug-eluting stents (DES). METHODS: Comparative studies published between January 2000 and February 2009 of the double stent technique vs. single stent technique with DES for true coronary bifurcations were identified using an electronic search and reviewed using a random effects

model. The primary endpoints of our study were side-branch and main-branch restenoses, all-cause mortality, myocardial infarction (MI) and target lesion revascularization (TLR) at longest available follow-up. The secondary endpoints of our analysis were postprocedural minimal luminal diameter (MLD) of the side branch and main branch, follow-up MLD of side branch and main branch and stent thrombosis. Heterogeneity was assessed and sensitivity analysis was performed to test the robustness of the overall summary odds ratios (ORs). RESULTS: Five studies comprising 1145 patients (616 single stent and 529 double stent) were included in the analysis. Three studies were randomized comparisons between the two techniques for true coronary bifurcation lesions. Incomplete reporting of data in the primary studies was common. The lengths of clinical and angiographic follow-up ranged between 6 and 12 months and 6 and 7 months, respectively. Postprocedural MLD of the side branch was significantly smaller in the single stent group [standardized mean difference (SMD) -0.71, 95% CI -0.88 to -0.54, P < 0.000, I2 = 0%]. The odds of side-branch restenosis (OR 1.11, 95% CI 0.47-2.67, P = 0.81, I2 = 76%), main-branch restenois (OR 0.88, 95% CI 0.56-1.39, P = 0.58, I = 0%), all-cause mortality (OR 0.52, 95% CI 0.11-2.45, P = 0.41, I2 = 0%), MI (OR 0.92, 95% CI 0.34-2.54, P = 0.87, I = 49%) and TLR (OR 0.87, 95% CI 0.46-1.65, P = 0.68, I2 = 0%) were similar between the two groups. Postprocedural MLD of the main branch [standardized mean difference (SMD) -0.08, 95% CI -0.42 to -0.26, P < 0.65, I2 = 67%], follow-up MLD of side branch (SMD -0.19, 95% CI -0.40 to 0.01, P < 0.31, I2 = 15%) and main branch MLD (SMD 0.17, 95% CI -0.18 to 0.542, P < 0.35, I2 = 65%) were also similar between the two groups. CONCLUSION: In patients undergoing percutaneous coronary intervention (PCI) for true coronary bifurcations, there is no added advantage of stenting both branches as compared with a conventional one-stent strategy. The results, however, need to be interpreted considering the poor study methods and/or poor quality of reporting in publications. We propose to move forward and consider the conduct of more systematic, well-designed and scientific trials to investigate the treatment of true coronary bifurcation lesions.

PMID: 19952947 [PubMed - indexed for MEDLINE]

10.

Circulation. 2009 Nov 17;120(20):1978-86. Epub 2009 Nov 2.

Comparison of plaque sealing with paclitaxel-eluting stents versus medical therapy for the treatment of moderate nonsignificant

saphenous vein graft lesions: the moderate vein graft lesion stenting with the taxus stent and intravascular ultrasound (VELETI) pilot trial.

Rodés-Cabau J, Bertrand OF, Larose E, Déry JP, Rinfret S, Bagur R, Proulx G, Nguyen CM, Côté M, Landcop MC, Boudreault JR, Rouleau J, Roy L, Gleeton O, Barbeau G, Noël B, Courtis J, Dagenais GR, Després JP, DeLarochellière R.

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Comment in:

- Circulation. 2009 Nov 17;120(20):1940-2.

Abstract

BACKGROUND: The presence of moderate saphenous vein graft (SVG) lesions is a major predictor of cardiac events late after coronary artery bypass grafting. We determined the effects of sealing moderate nonsignificant SVG lesions with paclitaxel-eluting stents (PES) on the prevention of SVG atherosclerosis progression. METHODS AND RESULTS: Patients with at least 1 moderate SVG lesion (30% to 60% diameter stenosis) were randomized either to stenting the moderate SVG lesion with a PES (n=30, PES group) or to medical treatment alone (n=27, medical treatment group). Patients had an angiographic and intravascular ultrasound evaluation of the SVG at baseline and at 12-month follow-up. The primary end points were (1) the ultrasound SVG minimal lumen area at follow-up and (2) the changes in ultrasound atheroma volume in an angiographically nondiseased SVG segment. Mean time from coronary artery bypass grafting was 12+/-6 years, and mean low-density lipoprotein cholesterol level was 73+/-31 mg/dL. A total of 70 moderate SVG lesions (39+/-7% diameter stenosis) were evaluated. Significant disease progression occurred in the medical treatment group at the level of the moderate SVG lesion (decrease in minimal lumen area from 6.3+/-3.0 to 5.6+/-3.1 mm(2); P<0.001), leading to a severe flow-limiting lesion or SVG occlusion in 22% of the patients compared with none in the PES group (P=0.014). In the PES group, mean minimal lumen area increased (P<0.001) from 6.1+/-2.2 to 8.6+/-2.9 mm(2) at follow-up (P=0.001 compared with the medical treatment group at 12 months). There were no cases of restenosis or stent thrombosis. No significant atherosclerosis progression occurred at the nonstented SVG segments. At 12-month follow-up, the cumulative incidence of major adverse cardiac events related to the target SVG was 19% in the medical treatment group versus 3% in the PES group

(P=0.091). CONCLUSIONS: Stenting moderate nonsignificant lesions in old SVGs with PES was associated with a lower rate of SVG disease progression and a trend toward a lower incidence of major adverse cardiac events at 1-year follow-up compared with medical treatment alone, despite very low low-density lipoprotein cholesterol values. This pilot study supports further investigation into the role of plaque sealing in SVGs. Clinical Trial Registration- URL: http://www.clinicaltrials.gov. Unique identifier: NCT002289835.

PMID: 19884468 [PubMed - indexed for MEDLINE]

11.

Heart Vessels. 2009 Sep;24(5):335-9. Epub 2009 Sep 27.

Effect of balloon inflation time on expansion of sirolimus-eluting stent.

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Abstract

There is little information about the relationship between balloon inflation time and sirolimus-eluting stent (SES) expansion. In this randomized intravascular ultrasound (IVUS) study, 92 de novo lesions in native coronary arteries that underwent SES implantation were enrolled. Sirolimus-eluting stent was implanted using an inflation pressure of 14 atm. Stent balloon was gradually inflated until 14 atm in 10 s. In the short inflation group, it was deflated immediately after an image of the balloon inflated at 14 atm was taken. Stent balloon inflation lasted 60 s in the long inflation group. Intravascular ultrasound was then performed. The long balloon inflation resulted in a larger stent cross-sectional area (4.9 +/- 1.6 mm(2) vs 4.3 +/- 1.4 mm(2), P < 0.05) and expansion (71% +/- 13% vs 60% +/- 13%, P < 0.001) compared to the short balloon inflation, although stent expansion was relatively low in both groups. The relatively longer balloon inflation time using an inflation pressure of 14 atm results in better SES expansion. However, in the majority of lesions, adequate stent expansion is not achieved even using long balloon inflation, if it is inflated at 14 atm.

PMID: 19784815 [PubMed - indexed for MEDLINE]

12.

Am Heart J. 2009 Oct;158(4):520-526.e2. Epub 2009 Aug 26.

SPIRIT IV trial design: a large-scale randomized comparison of everolimus-eluting stents and paclitaxel-eluting stents in patients with coronary artery disease.

Nikolsky E, Lansky AJ, Sudhir K, Doostzadeh J, Cutlip DE, Piana R, Su X, White R, Simonton CA, Stone GW.

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Abstract

BACKGROUND: In the 300-patient SPIRIT II and 1002-patient SPIRIT III randomized trials, the everolimus-eluting stent (EES) compared to the paclitaxel-eluting stent (PES) resulted in reduced angiographic late loss (a primary end point in both trials), noninferior rates of 9-month target vessel failure (a primary end point in SPIRIT III), and reduced rates of target lesion revascularization and major adverse cardiac events (secondary end points). However, neither trial was powered for superiority for clinical end points, and the routine performance of angiographic follow-up may have artificially exaggerated the absolute benefits of EES. The relative efficacy of these 2 stents in patients with diabetes mellitus also remains controversial. We therefore designed a large-scale randomized trial without angiographic follow-up to further assess the differences between these 2 stent platforms. STUDY DESIGN: SPIRIT IV is an ongoing prospective, active-controlled, single-blinded, multicenter clinical trial in which 3690 patients with native coronary artery disease have been randomized 2:1 to EES versus PES. Patients with up to 3 de novo native coronary artery lesions (maximum 2 lesions per epicardial vessel) with length <or=28 mm and reference vessel diameter >or=2.5 to <or=4.25 mm were enrolled at 66 US clinical sites. Clinical follow-up at 30, 180, and 270 days; 1 year; and then yearly for up to 5 years is underway. The primary end point is the rate of ischemia-driven target lesion failure at 1 year, a composite measure of safety and efficacy consisting of cardiac death, target vessel myocardial infarction, or ischemia-driven target lesion revascularization, with the trial powered for sequential noninferiority and superiority testing. SUMMARY: SPIRIT IV is the largest randomized comparison of 2 DES with completed enrollment. The absence of routine angiographic follow-up will allow an accurate

assessment of the absolute differences in the clinical safety and efficacy profile between these devices. The magnitude of the study will also permit significant insights to be gained into the relative performance of the 2 stents in important subgroups, including patients with diabetes mellitus.

PMID: 19781409 [PubMed - indexed for MEDLINE]

13.

Am J Cardiol. 2009 Sep 15;104(6):786-90. Epub 2009 Jul 21.

Comparison of long versus short ("spot") drug-eluting stenting for long coronary stenoses.

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Abstract

We compared spot drug-eluting stenting (DES) to full stent coverage for treatment of long coronary stenoses. Consecutive, consenting patients with a long (>20 mm) coronary lesion of nonuniform severity and indication for percutaneous coronary intervention were randomized to full stent coverage of the atherosclerotic lesion with multiple, overlapping stenting (full DES group, n = 90) or spot stenting of hemodynamically significant parts of the lesion only (defined as diameter stenosis >50%; spot DES group, n = 89). At 1-year follow-up, 14 patients with full DES (15.6%) and 5 patients (5.6%) with spot DES had a major adverse cardiac event (MACE; p = 0.031). At 3 years, MACEs occurred in 18 patients with full DES (20%) and 7 patients (7.8%) with spot DES (p = 0.019). Cox proportional hazard model showed that the risk for MACEs was almost 60% lower in patients with spot DES compared to those with full DES (hazard ratio 0.41, 95% confidence interval 0.17 to 0.98, p = 0.044). This association remained even after controlling for age, gender, lesion length, and type of stent used (hazard ratio 0.42, 95% confidence interval 0.17 to 1.00, p = 0.05). In conclusion, total lesion coverage with DES is not necessary in the presence of diffuse disease of nonuniform severity. Selective stenting of only the significantly stenosed parts of the lesion is an appropriate therapeutic alternative in this setting, offering a favorable clinical outcome.

PMID: 19733712 [PubMed - indexed for MEDLINE]

14.

Chin Med J (Engl). 2009 Jul 20;122(14):1603-9.

Different edge effects of paclitaxel- and sirolimus-eluting stents on proximal and distal edges in patients with unstable angina: serial intravascular ultrasound analysis.

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Abstract

BACKGROUND: It is unclear whether edge segments have different responses to paclitaxel eluting stent (PES) and sirolimus eluting stent (SES) implantation in patients with unstable angina. This study aimed to compare the different vascular edge responses in patients with unstable angina and single de novo coronary lesion treated with SES and PES. METHODS: Two hundred and fifty-five patients with unstable angina and single de novo lesion were randomly assigned to PES and SES groups. Serial volumetric intravascular ultrasound (IVUS) images were taken immediately after stenting and at an eight-month follow-up. Five-mm edge segments proximal and distal to the stents were analyzed. RESULTS: Baseline characteristics were comparable between the two groups. At proximal-edge segment, the vessel area decreased and the plaque area increased significantly in the PES group as compared with the SES group. A significant net loss of lumen area was found in the PES group (from (11.10 +/- 3.12) mm(2) at baseline to (9.92 +/- 3.59) mm(2) at the follow-up, $P < 0.001$). At the distal-edge segment, the net loss of lumen area in the PES group (from (7.71 +/- 2.81) mm(2) at baseline to (6.66 +/- 2.29) mm(2) at the follow-up, $P < 0.001$) was attributed to a significant increase of plaque area. Proximal-edge stenosis was commonly seen in the PES group (20.0%) as compared with the SES group (5.0%, $P = 0.001$). This correlated with the higher incidence of target lesion revascularization in the PES group ($P = 0.03$). Subsegmentally, the smallest Delta lumen area was located at 2 mm proximally in both groups, at 0 mm distally in the PES group, and at 1 mm distally in the SES group. CONCLUSIONS: The two groups demonstrated negative remodeling of edge segments. PES was less effective than SES in inhibiting the growth of plaque within the first 1-mm length proximal to the stent.

PMID: 19719958 [PubMed - indexed for MEDLINE]Free Article

15.

Heart. 2009 Oct;95(20):1676-81. Epub 2009 Jul 29.

Simple versus complex stenting strategy for coronary artery bifurcation lesions in the drug-eluting stent era: a meta-analysis of randomised trials.

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Abstract

BACKGROUND: Coronary bifurcation lesions remain a challenge for interventional cardiologists and the optimal stenting strategy has not been established in the current drug-eluting stent (DES) era. This study compared two strategies for DES treatment of coronary bifurcation lesions: a simple stenting approach (stenting only the main vessel (MV) and provisional stenting of the side branch (SB) only when bailout of the SB is necessary) versus a complex stenting approach (routinely stenting not only MV but also SB). METHODS: Data sources included PubMed and conference proceedings. Prespecified criteria were met by five randomised studies comparing simple stenting strategy versus complex stenting strategy in 1553 patients with coronary bifurcation lesions. Studies reported the clinical and angiographic outcomes of efficacy and safety during a minimum of 6 months. RESULTS: The risks of follow-up myocardial infarction (MI) (relative ratio (RR) 0.54, 95% confidence interval (CI) 0.37 to 0.78, p = 0.001) and early (in-hospital or 30-day) MI (RR 0.52, 95% CI 0.35 to 0.78, p = 0.002) were markedly lower in patients treated with the simple strategy compared to the complex strategy. There were no significant differences between the two different strategies with respect to the rates of cardiac death (RR 0.68, 95% CI 0.21 to 2.25, p = 0.53), target lesion revascularisation (TLR) (RR 0.93, 95% CI 0.62 to 1.41, p = 0.74) or definite stent thrombosis (ST) (RR 0.50, 95% CI 0.19 to 1.32, p = 0.16). The restenosis risk of MV and SB did not differ between the simple strategy group and the complex strategy group (RR 1.15, 95% CI 0.66 to 2.00, p = 0.63 and RR 1.12, 95% CI 0.80 to 1.57, p = 0.50, respectively). CONCLUSIONS: Compared to the complex strategy for DES treatment of coronary bifurcation lesions, the simple strategy was associated with a lower risk of early MI and a similar rate of angiographic restenosis. Since the complex strategy could not improve the clinical or angiographic

outcome, the simple strategy can be recommended as a preferred bifurcation stenting technique in the DES era.

PMID: 19643768 [PubMed - indexed for MEDLINE]

16.

Am J Cardiol. 2009 Jul 15;104(2):210-5. Epub 2009 May 18.

Timing, causes, and predictors of death after three years' follow-up in the Danish Multicenter Randomized Study of Fibrinolysis versus Primary Angioplasty in Acute Myocardial Infarction (DANAMI-2) trial.

Busk M, Maeng M, Kristensen SD, Thuesen L, Krusell LR, Mortensen LS, Steinmetz ER, Nielsen TT, Andersen HR; DANAMI-2 Investigators.

Collaborators (18)
Andersen HR, Nielsen TT, Rasmussen K, Thuesen L, Kelbaek H, Thayssen P, Abildgaard U, Pedersen F, Madsen JK, Grande P, Villadsen AB, Krusell LR, Haghfelt T, Lomholt P, Husted SE, Vigholt E, Kjaergard HK, Mortensen LS.

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Abstract

This study evaluated the timing, causes, and predictors of death during long-term follow-up after primary angioplasty with stent implantation versus in-hospital fibrinolysis with a tissue plasminogen activator (alteplase). We randomized 1,572 patients with ST-elevation myocardial infarction to primary angioplasty or alteplase and followed them for 3 years. The causes of death were prospectively assessed by an end point committee unaware of the study treatment. A total of 225 patients (14.3%) died, 113 within the first 30 days and 112 between 31 days and 3 years. The mortality and causes of death did not differ between the 2 treatments. The causes of death were cardiogenic shock/congestive heart failure (41%), sudden death (17%), other cardiac death (10%), cancer (12%), and other noncardiac death (20%). Cardiac death was predominant during the first month only (86% of early deaths), and noncardiac death and cardiac death were equally frequent after 30 days (49% and 51% of late deaths, respectively). Independent predictors of death after discharge were age, left ventricular ejection fraction, diabetes, Killip class, and a lack of treatment with a beta blocker or statin. In conclusion, the causes of death did not differ between alteplase treatment and primary angioplasty with

stent implantation. One half of the deaths within 3 years after ST-elevation myocardial infarction occurred during the first 30 days, and cardiac death was predominant during the first 30 days only.

- 17.

Am J Cardiol. 2009 Jul 1;104(1):46-51. Epub 2009 May 4.

Relation of genetic polymorphisms in the cytochrome P450 gene with clopidogrel resistance after drug-eluting stent implantation in Koreans.

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Abstract

Clopidogrel is a prodrug that has to be converted to an active metabolite by hepatic cytochrome P450 (CYP) isoenzymes to inhibit platelet aggregation. Individual variability of platelet inhibition by clopidogrel suggests a possibility for genetic factors having a significant influence on clopidogrel responsiveness. In this study, we sought to determine the relation of genetic polymorphisms of CYP genes to clopidogrel resistance in Koreans. Four hundred fifty patients who underwent successful percutaneous coronary intervention with drug-eluting stents were randomly assigned to treatment with dual antiplatelet regimen (aspirin plus clopidogrel) or triple antiplatelet regimen (aspirin plus clopidogrel plus cilostazol). Clopidogrel resistance using VerifyNow P2Y12 assay and genetic analysis were performed in 387 patients. Clopidogrel resistance was found in 112 patients (28.9%). In the clopidogrel-responsive group, there was a significantly higher proportion of cilostazol use. Because cilostazol showed a significant influence on clopidogrel resistance, we examined the association of single-nucleotide polymorphisms and clopidogrel resistance in the dual and triple antiplatelet therapy groups, respectively. In all subjects, the CYP2C19*3A allele was significantly more prevalent in the clopidogrel-resistant group compared with the clopidogrel-responsive group. Multiple logistic regression analysis demonstrated that CYP2C19*3 is an independent predictor of clopidogrel resistance. In conclusion, CYP2C19*3 single-nucleotide polymorphisms is an independent risk factor of clopidogrel resistance in Korean subjects with coronary artery disease.

PMID: 19576320 [PubMed - indexed for MEDLINE]

18.

Catheter Cardiovasc Interv. 2009 Nov 1;74(5):719-27.

Gender-based evaluation of the XIENCE V everolimus-eluting coronary stent system: clinical and angiographic results from the SPIRIT III randomized trial.

Lansky AJ, Ng VG, Mutlu H, Cristea E, Guiran JB, Midei M, Newman W, Sanz M, Sood P, Doostzadeh J, Su X, White R, Cao S, Sudhir K, Stone GW.

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Abstract

OBJECTIVES: We evaluated the role of gender on clinical and angiographic results of the everolimus-eluting stent in the SPIRIT III trial. BACKGROUND: The SPIRIT III trial demonstrated superior efficacy of the XIENCE V everolimus-eluting stent compared with the TAXUS paclitaxel-eluting stent. Whether these results are applicable to women is unknown. METHODS: A total of 1,002 patients with coronary artery lesions of 28 mm or less long in 2.5-3.75 mm diameter vessels were prospectively randomized to receive percutaneous coronary intervention with either XIENCE V stent or TAXUS stent placement. Post hoc gender subset analysis was performed. RESULTS: A total of 669 patients (200 women) received the XIENCE V stent, and 332 patients (114 women) were assigned to the TAXUS stent. Women were older and had more hypertension and diabetes than men. At 1 year, rates of MACE (11.1% vs. 5.7%, P = 0.004), TVF (13.7% vs. 7.5%, P = 0.003), TVR (10.8% vs. 4.6%, P = 0.0007), and TLR (7.2% vs. 2.7%, P = 0.002) were higher in women compared with men. The difference in 1 year MACE and TVF rates between men and women remained after adjusting for baseline covariates. Although the angiographic characteristics at baseline were similar among the female cohort, women assigned to XIENCE V had lower in-stent late loss (0.19 vs. 0.42 mm, P = 0.01) compared with women treated with the TAXUS stent. Although 30-day clinical outcomes were similar for women treated with XIENCE V and TAXUS stents, at 1 year, women with XIENCE V stents had significantly lower MACE (8.2% vs. 16.1 %, P = 0.04) and TVR (3.1% vs. 8.9%, P = 0.03) compared with those treated with TAXUS stents. Stent thrombosis rates were similar between women receiving either XIENCE V or TAXUS stents.

CONCLUSIONS: Women in the SPIRIT III trial had inherently higher MACE and TVF rates than men. However, the angiographic and clinical benefits of using XIENCE V stents are generalizable to women.

PMID: 19530147 [PubMed - indexed for MEDLINE]

Related citations

19.

Chin Med J (Engl). 2009 Apr 5;122(7):793-7.

A high maintenance dose of clopidogrel improves short-term clinical outcomes in patients with acute coronary syndrome undergoing drug-eluting stent implantation.

Han YL, Wang B, Li Y, Xu K, Wang SL, Jing QM, Wang ZL, Wang DM, Ma YY, Wang G.

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Abstract

BACKGROUND: Recurrent ischemic events occurred even during routine use of 75 mg clopidogrel in addition to aspirin, that indicated a potentially insufficient maintenance dosage of clopidogrel. The aim of the present study was to evaluate the short-term efficacy and safety of a 150 mg maintenance dose of clopidogrel following a 600 mg loading dose in patients with an acute coronary syndrome (ACS) undergoing drug eluting stent (DES) implantation. METHODS: Between November 2005 and November 2006, a total of 813 consecutive ACS patients undergoing DES implantation were enrolled. A 600 mg loading dose was administered before percutaneous coronary intervention (PCI) and patients were randomized to receive clopidogrel 75 mg or 150 mg for 30 days in addition to 300 mg aspirin daily. Primary end points were the composite of cardiac death, non-fatal myocardial infarction (MI) and urgent target vessel revascularization (UTVR). Secondary end points included stent thrombosis (ST), major and minor bleeding events at 30 days. RESULTS: At a follow-up period of 30 days, 4 (1.0%) patients in the 150 mg group and 9 (2.2%) patients in the 75 mg group ($P > 0.05$) reached the primary end points. There was no significant difference in the incidences of MI (0.5% vs 1.2%, $P > 0.05$), UTVR (0.7% vs

2.0%, P > 0.05), and cardiac death (0.2% vs 0.2%, P > 0.05) between the two groups. The incidence of ST (0 vs 1.5%, P < 0.05) was significantly lower in the 150 mg group than that in the 75 mg group. There were no significant differences between both groups regarding the risk of major (0.2% vs 0, P > 0.05) or minor (0.5% vs 0.2%, P > 0.05) bleedings. CONCLUSION: A high clopidogrel maintenance dose of 150 mg daily following a 600 mg loading dose for the first month after PCI procedure reduces the risk of ST and appears to be safe in patients with ACS undergoing DES implantation.

PMID: 19493391 [PubMed - indexed for MEDLINE]Free Article

Related citations

20.

Circulation. 2009 Jun 16;119(23):2986-94. Epub 2009 Jun 1.

Paclitaxel-coated balloon catheter versus paclitaxel-coated stent for the treatment of coronary in-stent restenosis.

Unverdorben M, Vallbracht C, Cremers B, Heuer H, Hengstenberg C, Maikowski C, Werner GS, Antoni D, Kleber FX, Bocksch W, Leschke M, Ackermann H, Boxberger M, Speck U, Degenhardt R, Scheller B.

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Comment in:

- Circulation. 2010 Feb 16;121(6):e33; author reply e34-5.

Abstract

BACKGROUND: Treatment of in-stent restenosis with paclitaxel-coated balloon catheter as compared with plain balloon angioplasty has shown surprisingly low late lumen loss at 6 months and fewer major adverse cardiac events up to 2 years. We compared the efficacy and safety of a paclitaxel-coated balloon with a paclitaxel-eluting stent as the current standard of care. METHODS AND RESULTS: One hundred thirty-one patients with coronary in-stent restenosis were randomly assigned to treatment by a paclitaxel-coated balloon (3 microg/mm2) or a paclitaxel-eluting stent. The main inclusion criteria encompassed diameter stenosis of > or =70% and < or =22 mm in length, with a vessel diameter of 2.5

to 3.5 mm. The primary end point was angiographic in-segment late lumen loss. Quantitative coronary angiography revealed no differences in baseline parameters. At 6 months follow-up, in-segment late lumen loss was 0.38+/-0.61 mm in the drug-eluting stent group versus 0.17+/-0.42 mm (P=0.03) in the drug-coated balloon group, resulting in a binary restenosis rate of 12 of 59 (20%) versus 4 of 57 (7%; P=0.06). At 12 months, the rate of major adverse cardiac events were 22% and 9%, respectively (P=0.08). This difference was primarily due to the need for target lesion revascularization in 4 patients (6%) in the coated-balloon group, compared with 10 patients (15%) in the stent group (P=0.15). CONCLUSIONS: Treatment of coronary in-stent restenosis with the paclitaxel-coated balloon was at least as efficacious and as well tolerated as the paclitaxel-eluting stent. For the treatment of in-stent restenosis, inhibition of re-restenosis does not require a second stent implantation.

PMID: 19487593 [PubMed - indexed for MEDLINE]

21.

Am J Cardiol. 2009 Jun 1;103(11):1551-5. Epub 2009 Apr 8.

Optical coherence tomographic results at six-month follow-up evaluation of the CATANIA coronary stent system with nanothin Polyzene-F surface modification (from the Assessment of The LAtest Non-Thrombogenic Angioplasty Stent [ATLANTA] trial).

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Abstract

Drug-eluting stents were devised as an answer to restenosis, but research has shown that the eluting drug can interfere with the blood vessel's healing process, thus increasing the risk of stent thrombosis. A stent coated with the new proprietary polymer Polyzene-F, is a novel technical solution that promises to decrease in-stent restenosis and tackle the risk of thrombosis. Fifty-five patients were enrolled in the first clinical human study (ATLANTA registry), addressing the short-term follow-up results of the CATANIA stent with Polyzene-F. As a part of the study protocol, 15 patients were randomly assigned to optical coherence tomographic (OCT) examination at 6-month follow-up. Optical coherence tomograms were obtained using a Lightlab M2 system with a motorized pull-back at 2.0 mm/s. OCT images were

acquired at 15.6 frames/s. A total of 1,904 cross-sectional images with 19,028 struts were analyzed. The rate of covered struts was 99.5%, whereas malapposed struts accounted for 0.15%. Area measurements were performed in 476 cross sections. Neointimal hyperplasia (NIH) area and percent NIH area were 3.2 +/- 1.4 mm2 and 38 +/- 17%, respectively. Percent NIH area was comparable between diabetics and nondiabetics. Qualitative assessment of OCT images demonstrated neither occurrence of stent fractures nor thrombus. In conclusion, OCT assessment of the Polyzene-F-covered stent at follow-up showed a small percentage of neointima. Also, almost complete stent strut coverage was revealed by optical coherence tomography. These figures indicate that the CATANIA stent with Polyzene-F is a promising solution for decreasing late stent restenosis and preventing thrombosis.

PMID: 19463514 [PubMed - indexed for MEDLINE]

22.

Eur J Cardiothorac Surg. 2009 Oct;36(4):611-5. Epub 2009 Apr 25.

Coronary artery bypass grafting versus drug-eluting stents in multivessel coronary disease. A meta-analysis on 24,268 patients.

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Comment in:

- Eur J Cardiothorac Surg. 2009 Oct;36(4):609-10.

Abstract

OBJECTIVE: Coronary artery bypass grafting (CABG) has been shown to provide better results than percutaneous coronary intervention (PCI) in multivessel coronary disease. Drug-eluting stents (DES) have significantly improved results of PCI in terms of restenosis but the advantages of such a treatment compared to CABG remain uncertain. This meta-analysis summarizes available data from observational cohorts comparing DES-PCI versus CABG. METHODS: We performed a systematic literature search for observational cohorts comparing CABG versus DES-PCI in patients with multivessel coronary disease. The mixed model method was used to obtain the pooled hazard ratio (HR) for outcomes of interest.

RESULTS: A total of nine observational nonrandomized studies were identified and analyzed including a total of 24,268 patients with multivessel coronary disease who underwent DES-PCI (n=13,540) and CABG (n=10,728). Mean follow-up time was 20 months. Pooled analysis showed that DES-PCI and CABG were comparable in terms of composite occurrence of death, acute myocardial infarction and cerebrovascular accidents (HR=0.94; 95% CI=0.72-1.22; p=0.66). However, there was a significantly higher risk of repeat revascularization in the DES-PCI group (HR=4.06; 95% CI=2.64-6.24; p<0.001). Overall major adverse cardiac and cerebrovascular events rate in the DES-PCI was higher compared to the CABG group (HR=1.86; 95% CI=1.36-2.54; p<0.001). CONCLUSIONS: In the 'real world' clinical practice, overall major adverse cardiac and cerebrovascular events rate continues to be higher after DES-PCI due to an excess of redo revascularization compared with CABG.

PMID: 19394857 [PubMed - indexed for MEDLINE]

23.

Am Heart J. 2009 May;157(5):818-24, 824.e1.

Evaluation of individualized clopidogrel therapy after drug-eluting stent implantation in patients with high residual platelet reactivity: design and rationale of the GRAVITAS trial.

Price MJ, Berger PB, Angiolillo DJ, Teirstein PS, Tanguay JF, Kandzari DE, Cannon CP, Topol EJ.

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Abstract

BACKGROUND: The inhibitory response to clopidogrel varies widely among individuals. Data suggest that patients with high residual platelet reactivity despite clopidogrel therapy are at greater risk for thrombotic events after percutaneous coronary intervention (PCI) with drug-eluting stents (DES). The Gauging Responsiveness with A VerifyNow assay--Impact on Thrombosis And Safety (GRAVITAS) trial is designed to evaluate whether tailored clopidogrel therapy using a point-of-care platelet function assay reduces major adverse cardiovascular events after DES implantation. STUDY DESIGN: GRAVITAS is an international, randomized, multicenter, double-blinded, placebo-controlled, clinical trial. Approximately 2,800 patients with stable angina/ischemia or non-ST-elevation acute coronary syndrome

undergoing PCI with DES will be enrolled. Patients with high residual platelet reactivity on clopidogrel therapy 12 to 24 hours post-PCI will be randomized to standard maintenance clopidogrel therapy (75 mg daily) or high-dose clopidogrel therapy (additional loading dose followed by 150 mg daily) for 6 months. A random sample of patients without high residual reactivity will be followed and treated with standard clopidogrel therapy for 6 months. The primary end point is the time to first occurrence of cardiovascular death, nonfatal myocardial infarction, or definite/probable stent thrombosis. Platelet function analyses will also be performed at 30 days and 6 months. Major safety end points include GUSTO severe and moderate bleeding unrelated to coronary artery bypass surgery. CONCLUSIONS: GRAVITAS is the first large-scale clinical trial designed to examine whether adjustment of clopidogrel therapy on the basis of platelet function testing using a point-of-care assay safely improves outcomes after PCI with DES.

- 24.

Am Heart J. 2009 May;157(5):811-817.e1.

Efficacy of Xience/promus versus Cypher in rEducing Late Loss after stENTing (EXCELLENT) trial: study design and rationale of a Korean multicenter prospective randomized trial.

Park KW, Yoon JH, Kim JS, Hahn JY, Cho YS, Chae IH, Gwon HC, Ahn T, Oh BH, Park JE, Shim WH, Shin EK, Jang YS, Kim HS.

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Abstract

BACKGROUND: The everolimus-eluting stent (EES) is a newly developed drug-eluting stent using the MULTILINK VISION stent platform combined with the drug everolimus contained in a polymer coating. Recently reported randomized trials have shown the noninferiority and subsequent superiority of the EES compared with the paclitaxel-eluting stent regarding in-stent late loss (LL) at 180 days. However, there have been no studies comparing head to head the EES with the sirolimus-eluting stent (SES), which has shown the least amount of LL among the previously released drug-eluting stent (DES). In addition, adjunctive antiplatelet therapy is a critical factor in optimizing long-term DES safety. Despite the recommendation of the American Heart Association/American College of Cardiology to maintain 12 months of dual antiplatelet therapy, there have been no prospective randomized trials comparing the

efficacy and safety of different durations. STUDY DESIGN: In the Efficacy of Xience/promus versus Cypher in rEducing Late Loss after stENTing (EXCELLENT) trial, approximately 1,400 patients are being prospectively and randomly assigned in a 2 x 2 factorial design according to the type of stent (EES vs SES) and the duration of dual antiplatelet therapy (6 vs 12 months). The primary end point is in-segment LL at 9 months for comparison of type of stent, and the coprimary end point is target vessel failure at 12 months for comparison of dual antiplatelet therapy duration. SUMMARY: The EXCELLENT trial is the largest study yet performed to directly compare the efficacy and safety of the EES versus the SES. In addition, this study will also address the issue of a 6- versus 12-month duration of dual antiplatelet therapy for post-percutaneous coronary intervention management.

PMID: 19376305 [PubMed - indexed for MEDLINE]

- 25.

Circ J. 2009 Jun;73(6):1111-8. Epub 2009 Apr 17.

Comparison of low vs moderate dose of atorvastatin in clopidogrel resistance after coronary stenting in Korean patients with acute coronary syndrome.

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Abstract

BACKGROUND: The effect of atorvastatin 10 mg vs 40 mg in clopidogrel resistance and clinical events after coronary stenting was compared in patients with acute coronary syndrome (ACS). METHODS AND RESULTS: Platelet aggregation was measured before clopidogrel administration and 4 h, 24 h, 5 days, and 8 months later in 130 ACS patients. Stented patients were randomly assigned to atorvastatin either 10 mg (n=65) or 40 mg (n=65), and received an oral loading dose of 300 mg of clopidogrel followed by 75 mg/day for 8 months. Measurement of platelet aggregation was done by the turbimetric method. The mean % changes in inhibition of platelet aggregation were 35.5 +/-8.3, 50.9 +/-10.1, 38.3 +/-8.3, 40.0 +/-6.8 in the Atorvastatin 10 mg Group and 31.0 +/-7.6, 43.7 +/-9.8, 45.0 +/-10.3, 43.5 +/-7.8 (4 h, 24 h, 5 days, and 8 months, respectively, after 300 mg of clopidogrel pretreatment) in the Atorvastatin 40 mg Group with no significant differences between the 2 groups. Cardiovascular events showed no

significant differences during the follow-up. CONCLUSIONS: Atorvastatin 10 mg or 40 mg co-administered with clopidogrel for 8 months did not affect the antiplatelet potency of clopidogrel and showed no significant differences in the clinical events in ACS patients.

PMID: 19372620 [PubMed - indexed for MEDLINE]Free Article

26.

Am J Cardiol. 2009 Apr 15;103(8):1083-8. Epub 2009 Mar 4.

Serial intravascular ultrasound analysis of peri-stent remodeling and proximal and distal edge effects after sirolimus-eluting or paclitaxel-eluting stent implantation in patients with diabetes mellitus.

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Abstract

Patients with diabetes have an increased risk of in-stent restenosis after coronary stent implantation. Serial intravascular ultrasound was used to study chronic arterial responses and edge effects after implantation of Cypher (Cordis, Johnson & Johnson, Miami Lakes, Florida) or Taxus (Boston Scientific, Maple Grove, Minnesota) stents in diabetic patients. Seventy-four diabetic patients were randomly assigned to Cypher or Taxus stent implantation. Intravascular ultrasound of 5-mm long segments immediately proximal and distal to the stent was performed after the procedure and at the 8-month follow-up. The increase in peri-stent external elastic membrane (EEM) volume was more pronounced in the Taxus group (292.4 +/- 132.6 to 309.5 +/- 146.8 mm(3)) than in the Cypher group (274.4 +/- 137.2 to 275.4 +/- 140.1 mm(3); p = 0.005). Peri-stent plaque volume increased in the Taxus group (152.5 +/- 73.7 to 166.1 +/- 85.1 mm(3)), but was unchanged in the Cypher group (153.5 +/- 75.5 to 151.5 +/- 75.8 mm(3); p = 0.002). In proximal and distal reference segments, mean lumen area decreased within the entire 5-mm edge segment (proximal and distal) because of plaque progression (distal, 5.5 +/- 3.6 to 5.8 +/- 3.7 mm(2); p = 0.097; proximal, 8.1 +/- 2.7 to 8.7 +/- 2.9 mm(2); p = 0.006) without remodeling (change in EEM) in the Taxus group. Conversely, there were no significant changes in reference-segment EEM or plaque areas in the Cypher group. In conclusion, in diabetic patients, Taxus stent

implantation was associated with increased (1) peri-stent EEM volume and peri-stent plaque, and (2) stent edge plaque progression accompanied by lumen reduction without remodeling. These findings were not seen in Cypher stents.

27.

Am Heart J. 2009 Apr;157(4):620-4.e2.

Rationale and design of a randomized, double-blind, placebo-controlled trial of 6 versus 12 months clopidogrel therapy after implantation of a drug-eluting stent: The Intracoronary Stenting and Antithrombotic Regimen: Safety And EFficacy of 6 Months Dual Antiplatelet Therapy After Drug-Eluting Stenting (ISAR-SAFE) study.

Byrne RA, Schulz S, Mehilli J, Iijima R, Massberg S, Neumann FJ, ten Berg JM, Schömig A, Kastrati A; Intracoronary Stenting and Antithrombotic Regimen: Safety And EFficacy of Six Months Dual Antiplatelet Therapy After Drug-Eluting Stenting (ISAR-SAFE) Investigators.

Collaborators (13)
Kastrati A, Mehilli J, M ten Berg J, Schulz S, Mann J, Hauschke D, Hoffmann F, Schmitt C, Poci D, Barthel P, Pinieck S, Byrne RA, Birkmeier A.

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Abstract

BACKGROUND: Concern regarding the rate of delayed acute stent thrombosis associated with drug-eluting stent (DES) treatment has resulted in upward revision of the advised duration of dual antiplatelet therapy after DES implantation by both European and United States guideline writing committees. In fact, the corroboration of an increased rate of late thrombotic events remains outstanding, and these clinical practice guidelines are limited by an inadequate evidence base on which to ground their recommendations. HYPOTHESIS: We postulate that a 6-month duration of clopidogrel therapy after DES implantation is associated with a clinical outcome that is not inferior to that of a 12-month therapy. STUDY DESIGN: The Intracoronary Stenting and Antithrombotic Regimen: Safety And EFficacy of Six Months Dual Antiplatelet Therapy After Drug-Eluting Stenting (ISAR-SAFE) is a multinational, double-blind, placebo-controlled, randomized trial designed to examine the effects of a 6-month duration of clopidogrel therapy after DES implantation compared to that of 12 months. Patients on clopidogrel therapy at 6 months after DES implantation will be randomized in a 1:1 fashion to discontinuation of

clopidogrel versus a further 6 months of treatment. The primary end point is a composite of death, myocardial infarction, stent thrombosis, stroke, or thrombolysis in myocardial infarction major bleeding. Clinical follow-up is scheduled at 9 months postrandomization (15 months postintervention). According to power calculations based on a noninferiority design, it is estimated that 6,000 patients are required to be enrolled. SUMMARY: There is clinical equipoise on the issue of optimal duration of dual antiplatelet treatment after percutaneous intervention with DES. The ISAR-SAFE trial aims to assess whether discontinuation of clopidogrel 6 months after DES implantation is noninferior to routine prolongation of such therapy out to 1 year.

PMID: 19332187 [PubMed - indexed for MEDLINE]

28.

N Engl J Med. 2009 Mar 5;360(10):961-72. Epub 2009 Feb 18.

Percutaneous coronary intervention versus coronary-artery bypass grafting for severe coronary artery disease.

Serruys PW, Morice MC, Kappetein AP, Colombo A, Holmes DR, Mack MJ, Ståhle E, Feldman TE, van den Brand M, Bass EJ, Van Dyck N, Leadley K, Dawkins KD, Mohr FW; SYNTAX Investigators.

Collaborators (191)
Mooney M, Kroshus T, Zijlstra F, Boonstra PW, Vermeersch P, Van Cauwelaert P, Glogar D, Grimm M, Den Heijer P, Vrakking MM, Stoler R, Henry AC, Zelman R, Rizzo R, Cannon LA, Vazales B, Koolen J, Schonberger JP, Carrié D, Fournial G, Eltchaninoff H, Bessou JP, Legrand V, Limet R, Marco J, Soula P, Berland J, Bessou JP, Darremont O, Fernandez G, Serruys PW, Kappetein AP, Feldman TE, Chedrawy E, Taussig A, Accola KD, Dobies D, Silver M, Gershlick AH, Spyt TJ, Horvath IG, Papp L, Wiemer M, Seifert D, Schuler G, Mohr FW, Santos Rodriguez I, Gonzalez Santos JM, Macaya C, Rodriguez E, Betriu A, Pomar JL, Ferreira C, Fragata J, Ruiz JM, Llamas PJ, Morice MC, Farge A, Ruzyllo W, Religa Z, Aschermann M, Tosovsky J, Bramucci E, d'Armini A, Suryapranata H, Bruinsma H, Bruinsma GJ, Presbitero P, Gallotti R, Berti S, Glauber M, Dudek D, Sadowski J, Banning A, Westaby S, Ho P, Chen J, Jensen J, Lockowandt U, Thomas MR, Desai JB, Boekstegers P, Reichart B, Hauptmann KE, Muller V, Rothman MT, MaGee P, Bode C, Beyersdorf F, Kellett MA, Kramer RS, Holmes DR, Schaff HV, Brown DL, Mack MJ, Edes I, Peterffy A, Drzewiecki J, Buszman P, Bochenek A, Hartmann F, Sievers H, Virtanen K, Harjula AL, Chang M, Kaplon R, Preda I, Tarr F, McGarry T, Lucas SK, de Bruyne B, Wellens F, Reimers B, Giacomin A, Guagliumi G, Ferrazzi P, Erglis A, Lacis R, Possati G, Crea F, Endresen K, Svennevig J, Minor R, Locher J, De Belder A, Forsyth A, Albertsson P, Wiklund L, Kiesz S, Otero C, Colombo A, Torracca L, Stine R, Azar H, Thuese L, Hostrup PN, Buckner K, Guber M, Wolschleger K, Heiser JC, Redwood S, Venn G, Suttorp M, van Boven WJ, Heyrich G, Deshpande A, Brown D, Seifert F, Heigert M, Unger F, Taeymans Y, Van Nooten G, Simon R, Cremer J, Meinertz T, Reichenspurner HC, Bocksch W, Rutsch W, Dohmen P, Dawkins KD, Livesey SA, James S, Stahle E, Olivecrona G, Ingemansson R, Horwitz P, Everett J, Mann T, Killinger W, Satler L, Boyce SW, Oldroyd KG, Berg G, Babikian VL, Birnbaum D, Carrel TP, Gorman M, Hanet C, Hess OM, Jansen EW, Kappelle LJ, Steg PG, Bassand JP, Clayton T, Faxon DP, Gersh BJ, Monro JL, Pocock S, Turina MI, Roy K, Pereda P.

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Abstract

BACKGROUND: Percutaneous coronary intervention (PCI) involving drug-eluting stents is increasingly used to treat complex coronary artery disease, although coronary-artery bypass grafting (CABG) has been the treatment of choice historically. Our trial compared PCI and CABG for treating patients with previously untreated three-vessel or left main coronary artery disease (or both). METHODS: We randomly assigned 1800 patients with three-vessel or left main coronary artery disease to undergo CABG or PCI (in a 1:1 ratio). For all these patients, the local cardiac surgeon and interventional cardiologist determined that equivalent anatomical revascularization could be achieved with either treatment. A noninferiority comparison of the two groups was performed for the primary end point--a major adverse cardiac or cerebrovascular event (i.e., death from any cause, stroke, myocardial infarction, or repeat revascularization) during the 12-month period after randomization. Patients for whom only one of the two treatment options would be beneficial, because of anatomical features or clinical conditions, were entered into a parallel, nested CABG or PCI registry. RESULTS: Most of the preoperative characteristics were similar in the two groups. Rates of major adverse cardiac or cerebrovascular events at 12 months were significantly higher in the PCI group (17.8%, vs. 12.4% for CABG; P=0.002), in large part because of an increased rate of repeat revascularization (13.5% vs. 5.9%, P<0.001); as a result, the criterion for noninferiority was not met. At 12 months, the rates of death and myocardial infarction were similar between the two groups; stroke was significantly more likely to occur with CABG (2.2%, vs. 0.6% with PCI; P=0.003). CONCLUSIONS: CABG remains the standard of care for patients with three-vessel or left main coronary artery disease, since the use of CABG, as compared with PCI, resulted in lower rates of the combined end point of major adverse cardiac or cerebrovascular events at 1 year. (ClinicalTrials.gov number, NCT00114972.) 2009 Massachusetts Medical Society

PMID: 19228612 [PubMed - indexed for MEDLINE]Free Article

29.

N Engl J Med. 2009 Jan 15;360(3):213-24.

Fractional flow reserve versus angiography for guiding percutaneous coronary intervention.

Tonino PA, De Bruyne B, Pijls NH, Siebert U, Ikeno F, van' t Veer M, Klauss V, Manoharan G, Engstrøm T, Oldroyd KG, Ver Lee PN, MacCarthy PA, Fearon WF; FAME Study Investigators.

Collaborators (94)
Pijls N, Fearon W, De Bruyne B, Tonino P, Pijls N, Fearon W, De Bruyne B, Siebert U, Tonino P, Eeckhout E, El Gamal M, Barbato E, Kern M, Hodgson J, Siebert U, Gothe R, Bornschein B, Fearon W, Ikeno F, Brinton T, Lee D, Williams S, Yeung A, Ver Lee P, Wiseman A, Crespo G, Fincke R, Vom Eigen P, Lim M, Longnecker R, Leesar M, Yalamanchili V, Ikram S, Ragosta M, Gimple L, Lipson L, Powers E, Oldroyd K, Lindsay M, Robb S, Watkins S, Manoharan G, Tierney P, MacCarthy P, Shah A, Thomas M, Hill J, Baumbach A, Wilde P, Nightingale A, Skyme-Jones A, Barnes E, Herzfeld I, Törnerud M, Alström P, Witt N, Schersten F, Bonnier J, Botman C, Brueren B, van Dantzig J, Koolen J, Michels H, Peels C, Pijls N, Tonino P, Klauss V, Rieber J, Schiele T, Leibig M, Sohn Y, Söllner J, Bojara W, Lindstaedt M, Yazar A, Riess G, Werner G, Engstrøm T, Kelbaek H, Jørgensen E, Helqvist S, Saunamäki K, Clemmensen P, Kastrup J, Rasmussen K, Frobert O, De Bruyne B, Melikian N, Bartunek J, Wyffels E, Heyndrickx G, Wijns W, Vanderheyden M, Batjoens H.

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Abstract

BACKGROUND: In patients with multivessel coronary artery disease who are undergoing percutaneous coronary intervention (PCI), coronary angiography is the standard method for guiding the placement of the stent. It is unclear whether routine measurement of fractional flow reserve (FFR; the ratio of maximal blood flow in a stenotic artery to normal maximal flow), in addition to angiography, improves outcomes. METHODS: In 20 medical centers in the United States and Europe, we randomly assigned 1005 patients with multivessel coronary artery disease to undergo PCI with implantation of drug-eluting stents guided by angiography alone or guided by FFR measurements in addition to angiography. Before randomization, lesions requiring PCI were identified on the basis of their angiographic appearance. Patients assigned to angiography-guided PCI underwent stenting of all indicated lesions, whereas those assigned to FFR-guided PCI underwent stenting of indicated lesions only if the FFR was 0.80 or less. The primary end point was the rate of death, nonfatal myocardial infarction, and repeat revascularization at 1 year. RESULTS: The mean (+/-SD) number of indicated lesions per patient was 2.7+/-0.9 in the angiography group and 2.8+/-1.0 in the FFR group (P=0.34). The number of stents used per patient was 2.7+/-1.2 and 1.9+/-1.3, respectively (P<0.001). The 1-year event rate was 18.3% (91 patients) in the angiography group and 13.2% (67 patients) in the FFR group (P=0.02). Seventy-eight percent of the patients in the angiography group were free from angina at 1 year, as compared with 81% of patients in the FFR group (P=0.20). CONCLUSIONS: Routine measurement of FFR in patients with multivessel coronary artery disease who are undergoing PCI with drug-eluting stents significantly reduces the rate of

the composite end point of death, nonfatal myocardial infarction, and repeat revascularization at 1 year. (ClinicalTrials.gov number, NCT00267774.) 2009 Massachusetts Medical Society

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- 30.

EuroIntervention. 2008 Aug;4(2):229-33.

Safety in simple versus complex stenting of coronary artery bifurcation lesions. The nordic bifurcation study 14-month follow-up results.

Jensen JS, Galløe A, Lassen JF, Erglis A, Kumsars I, Steigen TK, Wiseth R, Narbute I, Gunnes P, Mannsverk J, Meyerdierks O, Rotevatn S, Niemelä M, Kervinen K, Nikus K, Vikman S, Ravkilde J, James S, Aarøe J, Ylitalo A, Helqvist S, Sjögren I, Thayssen P, Virtanen K, Puhakka M, Airaksinen J, Thuesen L; Nordic-Baltic PCI Study Group.

Collaborators (75)
Thuesen L, Lassen JF, Aarøe J, Thayssen P, Kelbaek H, Helqvist S, Jensen JS, Galløe A, James S, Sjögren I, Steigen T, Mannsverk J, Meyerdierks O, Gunnes P, Rotevatn S, Wiseth R, Nikus K, Vikman S, Hartikainen J, Niemelä M, Kervinen K, Virtanen K, Airaksinen J, Ylitalo A, Erglis A, Kumsars I, Thuesen L, Lassen JF, Ravkilde J, Krusell LR, Bøtker HE, Jensen JS, Galløe A, Aarøe J, Helqvist S, Kelbaek H, Jørgensen E, Saunamäki K, Thayssen P, Hansen KN, Sjögren I, James S, Schersten F, Lindvall B, Olivecrona G, Hellsten L, Lundgren L, Pripp CM, Samad B, Kellerth T, Steigen T, Mannsverk J, Gunnes P, Meyerdierks O, Wiseth R, Rotevatn S, Endresen K, Niemelä M, Kervinen K, Nikus K, Vikman S, Ylitalo A, Virtanen K, Puhakka M, Airaksinen J, Erglis A, Kumsars I, Hansen HR, Bargsteen H, Frydensberg D, Esbjerg M, Mortensen LS, Højdahl H, Thygesen K, Ravkilde J.

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Abstract

AIMS: The risk of stent thrombosis has been reported to increase with percutaneous coronary intervention (PCI) complexity. The present study reports the pre-specified secondary endpoint of a 14-month stent thrombosis and major adverse cardiac events in patients stented with a simple versus a complex bifurcation technique using sirolimus eluting stents (SES). METHODS AND RESULTS: A total of 413 patients with a coronary bifurcation lesion were randomised to a simple treatment strategy; stenting of main vessel and optional stenting of side branch (MV group), or to a complex stenting strategy; stenting of both main vessel and side branch (MV+SB group). Mortality data were available in all patients and 14-month clinical follow-up data in 395 (96%) of the patients. After 14 months, the rates

of definite, probable and possible stent thrombosis (ARC criteria) were 1.0% vs. 0.5%, 1.0% vs. 0% and 0.5% vs. 0% (ns) in the MV and in the MV+SB groups, respectively. Rates of MACE were 9.5% in the MV group and 8.2% in the MV+SB group (ns). Total death was seen in 2.4% vs. 1.0% and non-PCI related myocardial infarction in 2.0% vs. 1.0% in the MV and the MV+SB groups, respectively. CONCLUSIONS: After 14 months, two months after recommended cessation of dual antiplatelet therapy, the rates of stent thrombosis and major adverse cardiac events were low and independent of treatment complexity in patients treated with SES for coronary artery bifurcation lesions.

PMID: 19110788 [PubMed - indexed for MEDLINE]

31.

Circulation. 2009 Jan 6;119(1):71-8. Epub 2008 Dec 22.

Randomized study of the crush technique versus provisional side-branch stenting in true coronary bifurcations: the CACTUS (Coronary Bifurcations: Application of the Crushing Technique Using Sirolimus-Eluting Stents) Study.

Colombo A, Bramucci E, Saccà S, Violini R, Lettieri C, Zanini R, Sheiban I, Paloscia L, Grube E, Schofer J, Bolognese L, Orlandi M, Niccoli G, Latib A, Airoldi F.

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Comment in:

- Circulation. 2009 Aug 25;120(8):e63; author reply e64.

Abstract

BACKGROUND: Sirolimus-eluting stents have been reported to be effective in the treatment of coronary bifurcations. Still, it has not been fully clarified which strategy would provide the best results with true bifurcation lesions. METHODS AND RESULTS: The CACTUS trial (Coronary bifurcations: Application of the Crushing Technique Using Sirolimus-eluting stents) is a prospective, randomized, multicenter study comparing 2 different techniques of stenting, with mandatory final kissing-balloon inflation, in true bifurcations: (1) elective "crush" stenting and (2) stenting of only the main branch, with provisional side-branch T-stenting. From August 2004 to June 2007, 350 patients were enrolled in 12 European centers.

The primary angiographic end point was the in-segment restenosis rate, and the primary clinical end point was the occurrence of major adverse cardiac events (cardiac death, myocardial infarction, or target-vessel revascularization) at 6 months. At 6 months, angiographic restenosis rates were not different between the crush group (4.6% and 13.2% in the main branch and side branch, respectively) and the provisional stenting group (6.7% and 14.7% in the main branch and side branch, respectively; P=NS). Additional stenting on the side branch in the provisional stenting group was required in 31% of lesions. Rates of major adverse cardiac events were also similar in the 2 groups (15.8% in the crush group versus 15% in the provisional stenting group, P=NS). CONCLUSIONS: In most bifurcations with a significant stenosis in both branches, a provisional strategy of stenting the main branch only is effective, with the need to implant a second stent on the side branch occurring in approximately one third of cases. The implantation of 2 stents does not appear to be associated with a higher incidence of adverse events at 6 months.

PMID: 19103990 [PubMed - indexed for MEDLINE]Free Article

32.

Womens Health (Lond Engl). 2008 Sep;4(5):439-43.

XIENCE V SPIRIT WOMEN clinical trial: characterization of the female population undergoing stent implantation.

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Abstract

The XIENCE V SPIRIT WOMEN study will focus on specific aspects of women's health in relation to coronary artery disease, such as menopausal status, use of hormonal contraceptives or their surrogates, and the referral path and symptoms at presentation. The study is a prospective, open-label, single-arm, multicenter study designed to evaluate the performance of the XIENCE V Everolimus-Eluting Coronary Stent System in the treatment of female patients with coronary artery lesions. It also includes a prospective, single-blind, double-arm, randomized, multicenter substudy, in which patients will be randomized in a 2:1 ratio between the XIENCE V stent and the CYPHER Plus. In total,

approximately 2000 female patients, derived from the general interventional cardiology population, will be enrolled from up to 130 sites outside of the USA.

PMID: 19072483 [PubMed - indexed for MEDLINE]

33.

Int J Cardiol. 2010 Feb 18;139(1):80-91. Epub 2008 Nov 22.

Coronary bifurcation lesions: to stent one branch or both? A meta-analysis of patients treated with drug eluting stents.

Niccoli G, Ferrante G, Porto I, Burzotta F, Leone AM, Mongiardo R, Mazzari MA, Trani C, Rebuzzi AG, Crea F.

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Abstract

BACKGROUND: In the treatment of coronary bifurcation lesions (CBL), with drug eluting stents (DES), we sought to compare angiographic and clinical outcomes of a simple strategy of stenting main vessel only with balloon dilatation of the side branch with a complex strategy of stenting both branches. METHODS: We performed a meta-analysis of six studies, randomized (three) or prospective observational (three), including 963 patients, that directly compared the simple strategy to the complex strategy, in the treatment of CBL with DES. RESULTS: Final minimal lumen diameter (MLD) of the side branch was significantly smaller in the simple strategy group [WMD -0.50 mm, 95% CI (-0.76, -0.24), p<0.00001]. The risk of main vessel restenosis [RR 0.66, 95% CI (0.38-1.17), p=0.16], side branch restenosis [RR 0.62, 95% CI (0.24-1.56), p=0.31], follow up death [RR 0.60, 95% CI (0.19-1.86), p=0.38], follow up myocardial infarction [RR 0.71, 95% CI (0.46-1.10), p=0.13], or target vessel revascularization [RR 0.90, 95% CI (0.56-1.46), p=0.67] was similar between the two strategies. The simple strategy showed a trend to a lower risk of early myocardial infarction [RR 0.65, 95% CI (0.41-1.05), p=0.08]. CONCLUSION: In the treatment of unselected CBL with DES, the complex strategy does not penalize angiographic and clinical outcomes compared to the simple strategy. Further randomized studies are needed to assess the benefit of simple or complex strategy in the treatment of specific subsets of bifurcated lesions.

PMID: 19027969 [PubMed - indexed for MEDLINE]

34.

Coron Artery Dis. 2009 Jan;20(1):65-70.

Impact of direct sirolimus-eluting stent implantation on the early systemic inflammatory response compared with complementary stent implantation.

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Abstract

BACKGROUND: Systemic inflammation after percutaneous coronary intervention (PCI) identifies patients at increased risk of subsequent major adverse cardiac event. During PCI, the technique of stent implantation including direct stenting (DS) and complementary stenting (CS) is guided using both clinical and angiographic features. DS was practiced with increased frequency during PCI in an attempt to reduce both restenosis and major adverse cardiac event in the drug-eluting stent (DES) era. Impact of DS on the early inflammatory response has, however, not been investigated. We hypothesized that a direct DES implantation may attenuate the early inflammatory response compared with CS. PURPOSE: In this study, therefore, we prospectively select the sirolimus-eluting stent (SES) as a model of DESs, and sought to determine the early systemic inflammatory response in patients with single-vessel disease after PCI using either DS or CS techniques. METHODS: Thirty-nine patients who had single-vessel disease implanted with SES were randomly enrolled into the two groups: DS group (n=20) or CS group (n=19). The blood samples were taken before PCI, 24 and 72 h after stenting. The plasma concentrations of C-reactive protein and interleukin-6 (IL-6) were determined by enzyme-linked immunosorbent assay. RESULTS: No significant difference in baseline clinical, angiographic, and inflammatory parameters between the two groups is observed. The plasma IL-6 levels at 24 h after stent implantation were significantly higher than that at baseline in both groups ($P<0.05$, respectively). Plasma IL-6 level was, however, higher in CS group than in DS group ($P<0.01$) and was returned to baseline levels in both groups at 72 h after stenting. Meanwhile, the plasma levels of C-reactive protein were also significant higher in CS group compared with DS group at both 24 and 72 h after stenting ($P<0.05$,

respectively). CONCLUSION: Taken together, our findings demonstrated that a direct SES implantation significantly attenuated the early systemic inflammatory response in patients with single-vessel disease compared with CS technique.

PMID: 19018239 [PubMed - indexed for MEDLINE]

Related citations

35.

Cardiovasc Drugs Ther. 2009 Apr;23(2):137-43. Epub 2008 Nov 19.

Comparison of changes in early inflammatory markers between sirolimus- and paclitaxel-eluting stent implantation.

Li JJ, Yan HB, Xiang XP, Qin XW, Zhang CY.

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Comment in:

- Cardiovasc Drugs Ther. 2009 Apr;23(2):103-5.

Abstract

BACKGROUND: Systemic inflammation after coronary intervention identifies patients at increased risk of subsequent cardiac events. Cardiac events, especially in-stent restenosis, are less frequent after use of sirolimus-eluting stent (SES) compared with paclitaxel-eluting stent (PES). However, the underlying mechanism for this disparity is not well investigated. We hypothesize that an attenuated inflammatory response after SES implantation may be a contributor. PURPOSE: In the present study, we sought to determine the early inflammatory response after SES implantation in patients with single-vessel disease compared with PES implantation, and evaluate the relationship between inflammatory response and late clinical outcomes in a randomized design. METHODS: Thirty-two patients with stable angina were randomly enrolled into the two groups, SES or PSE group (n = 16 respectively). Peripheral blood samples were taken before PCI, 24 and 72 h after stenting. The plasma concentrations of C-reactive

protein (CRP) and interleukin-6 (IL-6) were determined by enzyme-linked immunosorbent assay (ELISA). The clinical and angiographic follow-up was performed at 8 months after stenting. RESULTS: The data showed that there was no significant difference in clinical and angiographic baseline characteristics between the two groups. The plasma CRP and IL-6 levels at 24 h after stenting were significant higher in both groups compared with baseline ($p < 0.01$ respectively). Likewise, the CRP levels at 72 h after stenting were also significant higher compared with baseline in both groups ($p < 0.01$ respectively). However, the plasma levels of IL-6 at 24 h and CRP at 72 h after stenting were higher in PES group compared with SES group ($p < 0.05$). At 8 months follow-up, the rates of major adverse cardiac events, target lesion revascularization, in-stent and in-segment restenosis were similar in both groups. However, the late loss in both in-stent and in-segment was significantly higher in the PES group than in SES group ($p < 0.001$ respectively). CONCLUSIONS: Our findings suggest that a drug-eluting stent implantation could trigger a systemic inflammatory response as previously demonstrated. However, SES implantation results in a lower inflammatory response compared with PES implantation, which seems to be associated with greater late of in-stent and in-segment loss at 8-month follow-up with PES.

36.

Eur Heart J. 2008 Dec;29(23):2868-76. Epub 2008 Nov 11.

Culotte stenting technique in coronary bifurcation disease: angiographic follow-up using dedicated quantitative coronary angiographic analysis and 12-month clinical outcomes.

Adriaenssens T, Byrne RA, Dibra A, Iijima R, Mehilli J, Bruskina O, Schömig A, Kastrati A.

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Comment in:

- Eur Heart J. 2008 Dec;29(23):2831-2.

Abstract

AIMS: Percutaneous treatment of coronary bifurcation disease remains challenging. In patient subsets in which a two-stent strategy is necessary, the culotte technique is a widely used method. We sought to examine the clinical and angiographic outcomes of patients treated in this manner at our institution. As quantitative coronary angiographic analysis using standard measurement programmes is problematic, we used a dedicated bifurcation analysis system. METHODS AND RESULTS: We prospectively enrolled patients undergoing culotte stenting with drug-eluting stents (Cypher, Endeavor, polymer-free rapamycin-eluting, Taxus) in two German centres. Lesions were classified according to the Medina classification. Angiographic follow-up was scheduled between 6 and 12 months post-index procedure. Clinical follow-up was available up to 12 months. Culotte technique was used in 134 lesions in 132 patients. Of these, 124 (92.5%) represented 'true bifurcation' lesion morphology. Kissing balloon inflation was used in 62% of patients. Procedural angiographic success was achieved in all lesions. Follow-up coronary angiography was performed in 108 (81.8%) patients. Median (IQR) late lumen loss was 0.10 (-0.04-0.38) mm in the proximal main vessel, 0.34 (0.03-0.66) mm in the distal main branch, and 0.30 (-0.01-0.72) mm in the side branch. The incidence of binary angiographic restenosis was 22% for the whole bifurcation lesion, 0% in the proximal main vessel, 9.1% in the distal main branch, and 16% in the side branch. At 12 months, 28 of 132 (21%) patients had undergone target lesion revascularization. The incidence of stent thrombosis (at 1 year) was 1.5%. Predictors of angiographic restenosis were older age, increasing bifurcation angle, more severe distal main branch stenosis, and smaller side branch reference diameter; kissing balloon post-dilatation tended to have a protective effect. CONCLUSION: The culotte stenting technique is associated with high procedural success and a relatively low risk of angiographic restenosis. Safety results in our cohort were favourable in terms of a low risk of stent thrombosis.

PMID: 19001472 [PubMed - indexed for MEDLINE]Free Article

37.

J Am Coll Cardiol. 2008 Nov 11;52(20):1621-7.

Long-term clinical benefit of sirolimus-eluting stents in patients with in-stent restenosis results of the RIBS-II (Restenosis Intra-stent: Balloon angioplasty vs. elective sirolimus-eluting Stenting) study.

Alfonso F, Pérez-Vizcayno MJ, Hernández R, Bethencourt A, Martí V, López-Mínguez JR, Angel J, Iñiguez A, Morís C, Cequier A, Sabaté M, Escaned J, Jiménez-Quevedo P, Bañuelos C, Suárez A, Macaya C; RIBS-II Investigators.

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Abstract

OBJECTIVES: We sought to assess the long-term effectiveness and safety of sirolimus-eluting stents (SES) in patients with in-stent restenosis (ISR). BACKGROUND: Treatment of patients with ISR remains a challenge. The long-term outcome of patients with ISR treated with SES remains unknown. METHODS: The RIBS-II (Restenosis Intra-stent: Balloon angioplasty vs. elective sirolimus-eluting Stenting) study was a randomized trial conducted in 150 patients with ISR (76 SES, 74 balloon angioplasty [BA]). The long-term (>1 year) clinical outcome and pre-specified subgroup analyses were pre-defined secondary study end points. RESULTS: At 1 year, the event-free survival (death, myocardial infarction, target vessel revascularization [TVR]) was better in the SES group (88% vs. 69%, $p < 0.005$). Additional long-term (>3 years) clinical follow-up was obtained in 97% of patients (median 3.3 years). After the first year, 3 patients died (1 SES, 2 BA), 5 suffered myocardial infarction (4 SES, 1 BA), and 7 required TVR (4 SES, 3 BA). At last follow-up, definitive/probable/possible stent thrombosis was similar in both groups (2/2/1 SES vs. 1/0/3 BA, p = NS). At 4 years, the event-free survival was 76% in the SES arm and 65% in the BA arm ($p = 0.019$). On multivariate analysis, SES implantation was an independent predictor of event-free survival. Subgroup analyses were consistent with the main outcome measure. CONCLUSIONS: In patients with ISR, SES implantation remains effective and safe at very long-term clinical follow-up.

PMID: 18992651 [PubMed - indexed for MEDLINE]

38.

Eur Heart J. 2008 Dec;29(24):2972-80. Epub 2008 Oct 21.

Randomized comparison between tirofiban and abciximab to promote complete ST-resolution in primary angioplasty: results of the facilitated angioplasty with tirofiban or abciximab (FATA) in ST-elevation myocardial infarction trial.

Marzocchi A, Manari A, Piovaccari G, Marrozzini C, Marra S, Magnavacchi P, Sangiorgio P, Marinucci L, Taglieri N, Gordini G, Binetti N, Guiducci V, Franco N, Reggiani ML, Saia F; FATA Investigators.

Collaborators (25)
Marzocchi A, Manari A, Piovaccari G, Marrozzini C, Marzocchi A, Manari A, Piovaccari G, Gordini G, Binetti N, Sangiorgio P, Saia F, Marzocchi A, Manari A, Piovaccari G, Marrozzini C, Taglieri N, Petri B, Taglieri N, Ovi V, Taglieri N, Silenzi S, Virzì S, Bacchi-Reggiani ML, Schembari A, Guastaroba P.

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Abstract

AIMS: To test the equivalence of high-dose bolus (HDB) tirofiban vs. abciximab during primary percutaneous coronary intervention (PPCI) in terms of ST-segment resolution (STR). METHODS AND RESULTS: The FATA trial (Facilitated Angioplasty with Tirofiban or Abciximab) was a prospective, multicentre, open-label trial that enrolled 692 patients with ST-segment elevation myocardial infarction (STEMI) undergoing PPCI. Patients were randomized 1:1 to receive abciximab (n = 341) or HDB tirofiban (n = 351). Primary endpoint was the rate of complete (> or =70%) STR 90 min after first balloon inflation. Thirty-day incidence of major bleedings, death, re-infarction and new revascularizations was also evaluated. Baseline characteristics of the two groups were well-balanced, with the exception of previous MI rates (tirofiban 6% vs. abciximab 2.6%, P = 0.03). The procedure was successful in 96.7% of the abciximab and in 96.6% of the tirofiban cohort (P = 0.94). Complete STR was obtained in 67.05% of the tirofiban and 70.45% of the abciximab group (Delta -3.4%, 95% confidence interval -10.35 to +3.56), which falls beyond the predefined Delta +/- 10% equivalence boundaries. Rates of secondary endpoints were similar between the two groups. CONCLUSION: This study failed to show the equivalence of HBD of tirofiban and abciximab as adjunctive therapy to PPCI.

PMID: 18940887 [PubMed - indexed for MEDLINE]Free Article

39.

Am Heart J. 2008 Oct;156(4):751.e1-7.

Systemic exposure of everolimus after stent implantation: a pharmacokinetic study.

Wiemer M, Seth A, Chandra P, Neuzner J, Richardt G, Piek JJ, Desaga M, Macaya C, Bol CJ, Miquel-Hebert K, De Roeck K, Serruys PW.

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Abstract

OBJECTIVES: We evaluated the pharmacokinetics of the eluted everolimus by assessing systemic drug release and distribution of everolimus-eluting stents. BACKGROUND: Drugs eluted by a coronary stent might cause adverse events such as tumors, infections, or noncardiac death. The systemic exposure of the drugs is unknown because there are only limited data about pharmacokinetics of drug-eluting stents in humans. METHODS: Venous blood samples in a subset of 39 patients were drawn just before implantation of the first stent (baseline, 0-minute time point) and at 10 and 30 minutes and 1, 2, 4, 6, 12, 24, 36, 48, 72, 168, and 720 hours (30 days) after completion of implantation of the last stent. Whole blood concentrations of everolimus were determined using a sensitive validated high-performance liquid chromatography mass spectrometry/mass spectrometry method. RESULTS: The total dose of everolimus received by the patients ranged from 53 to 588 microg. The last time point up to which whole blood concentrations could be quantified ranged per patient from 4 to 720 hours after implantation of the last stent. Across all dose levels, individual T(max) values ranged from 0.13 and 2.17 hours; individual C(max) ranged from 0.14 to 2.79 ng/mL. CONCLUSION: This study confirms the limited exposure to the systemic circulation of the eluted drug with the use of the XIENCE V Everolimus-Eluting Coronary Stent System (Abbott Vascular, Santa Clara, CA). Therefore, a systemic cause of adverse events is unlikely.

PMID: 18926156 [PubMed - indexed for MEDLINE]

Related citations

40.

Eur Heart J. 2008 Dec;29(23):2859-67. Epub 2008 Oct 9.

Randomized trial on routine vs. provisional T-stenting in the treatment of de novo coronary bifurcation lesions.

Ferenc M, Gick M, Kienzle RP, Bestehorn HP, Werner KD, Comberg T, Kuebler P, Büttner HJ, Neumann FJ.

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Comment in:

- Eur Heart J. 2008 Dec;29(23):2829-30.

Abstract

AIMS: We investigated whether routine T-stenting reduces restenosis of the side branch as compared with provisional T-stenting in patients with de novo coronary bifurcation lesions. METHODS AND RESULTS: Our randomized study assigned 101 patients with a coronary bifurcation lesion to routine T-stenting with sirolimus-eluting stents (SES) in both branches and 101 patients to provisional T-stenting with SES placement in the main branch followed by kissing-balloon angioplasty and provisional SES placement in the side branch only for inadequate results. Primary endpoint was per cent diameter stenosis of the side branch at 9 month angiographic follow-up. Angiographic follow-up in 192 (95%) patients revealed a per cent stenosis of the side branch of 23.0 +/- 20.2% after provisional T-stenting (19% with side-branch stent) and of 27.7 +/- 24.8% (P = 0.15) after routine T-stenting (98.2% with side-branch stent). The corresponding binary restenosis rates were 9.4 and 12.5% (P = 0.32), prompting re-intervention in 5.0 and 7.9% (P = 0.39), respectively. In the main branch, binary restenosis rates were 7.3% after provisional and 3.1% after routine T-stenting (P = 0.17). The overall 1 year incidence of target lesion re-intervention was 10.9% after provisional and 8.9% after routine T-stenting (P = 0.64). CONCLUSIONS: Routine T-stenting with SES did not improve the angiographic outcome of percutaneous coronary intervention of coronary bifurcation lesions as compared with stenting of the main branch followed by kissing-balloon angioplasty and provisional side-branch stenting.

PMID: 18845665 [PubMed - indexed for MEDLINE]PMCID: PMC2638653Free PMC Article

41.

Eur Heart J. 2008 Nov;29(22):2733-41. Epub 2008 Oct 2.

Neointimal hyperplasia after sirolimus-eluting and paclitaxel-eluting stent implantation in diabetic patients: the Randomized Diabetes and Drug-Eluting Stent (DiabeDES) Intravascular Ultrasound Trial.

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Abstract

AIMS: Patients with diabetes have increased risk of in-stent restenosis after coronary stent implantation owing to neointimal hyperplasia (NIH). The aim of the study was to evaluate the extent and distribution of NIH with intravascular ultrasound (IVUS) after coronary artery stenting with sirolimus-eluting (Cypher) or paclitaxel-eluting (Taxus) stents in diabetic patients. METHODS AND RESULTS: One hundred and thirty diabetic patients were randomized to Cypher or Taxus stent implantation. IVUS was performed at 8 month follow-up. NIH volume was significantly reduced in the Cypher group when compared with the Taxus group: median (inter-quartile range) 0.0 (0.0-0.0) vs. 8.0 mm(3) (0.1-33.0), P < 0.001. Per cent NIH volume was also significantly lower in Cypher stents compared with Taxus stents: median (inter-quartile range) 0.0 (0.0-0.0) vs. 7.5% (0.1-27.0), P < 0.001. NIH was covering 5.4% of the stent length in the Cypher stents compared with 46.1% in the Taxus stents (P < 0.001). The incidence of diffuse NIH was significantly higher for Taxus than for Cypher stents (42.9 vs. 3.5%, P < 0.001). Taxus stents had more often NIH at the proximal stent edge compared with Cypher stents (45.1 vs. 7%, P < 0.001) and no Cypher stents had NIH at the distal stent edge compared with 35.5% of the Taxus stents (P < 0.001). CONCLUSION: In diabetic patients, the Cypher stent, compared with the Taxus stent, inhibited NIH more effectively and had a more focal NIH pattern including less involvement of the stent edges.

PMID: 18832385 [PubMed - indexed for MEDLINE]Free Article

42.

Heart. 2009 Jun;95(12):970-5. Epub 2008 Sep 4.

Comparison of inflammatory markers and angiographic outcomes after implantation of sirolimus and paclitaxel-eluting stents.

Kang WC, Ahn TH, Moon CI, Han SH, Shin EK, Kim JS, Ko YG, Choi D, Jang Y, Kim BK, Oh SJ, Jeon DW, Yang JY.

Division of Cardiology, Gil Medical Center, Gachon University of Medicine and Science, Namdong-Gu, Incheon, Korea. kangwch@gilhospital.com

Comment in:

- Heart. 2009 Jun;95(12):957-9.

Abstract

OBJECTIVE: We compared the degree of systemic inflammation and its relation to the angiographic outcomes after drug-eluting stent (DES) implantations. METHODS: We implanted a single DES in 79 stable angina patients (50 men; 60.4 (9.5) years of age; sirolimus-eluting stent (SES), n = 38; paclitaxel-eluting stent (PES), n = 41). The high-sensitivity C-reactive protein (hs-CRP) and interleukin 6 (IL-6) levels were determined before and at 24 hours, 72 hours, and 4 weeks after the percutaneous coronary intervention (PCI). An angiography and intravascular ultrasound (IVUS) were performed. RESULTS: The hs-CRP and IL-6 levels at baseline did not differ between the two groups. The hs-CRP increased significantly from baseline at 24 hours and 72 hours after the PCI in both groups and there was a significant increase in the IL-6 level at 24 hours after the PCI in both groups. However, there was no significant difference between the two groups in any of the hs-CRP or IL-6 measurements. At follow-up, the late lumen loss was significantly higher in the PES group than in the SES group (0.57 (0.56) mm vs 0.28 (0.58) mm, respectively, p = 0.020). The neointimal hyperplasia (NIH) volume in the PES group was significantly higher than that in the SES group (23.1 (22.7) vs 3.8 (7.1) mm(3), respectively, p = 0.000). The percentage luminal volume reduction was higher in the PES group than in the SES group (18.9 vs 3.9%, p = 0.002). The absolute values or change in the inflammatory markers did not correlate with the NIH or stent volume reduction. CONCLUSIONS: Our study showed that the benefits obtained from the SES, which reduce neointimal proliferation, are not probably mediated by the attenuation of the systemic inflammatory markers hs-CRP or IL-6.

PMID: 18772180 [PubMed - indexed for MEDLINE]

43.

J Cardiovasc Med (Hagerstown). 2008 Sep;9(9):957-62.

A randomized trial comparing eptifibatide vs. placebo in patients with diffuse coronary artery disease undergoing drug-eluting stent implantation: design of the INtegrilin plus STenting to Avoid myocardial Necrosis Trial.

Biondi-Zoccai GG, Valgimigli M, Sheiban I, Margheri M, Marzocchi A, Prati F, Vischi M, Lettieri C, Violini R, Sardella G, Stabile A, Clementi F, Romeo F, Colombo A, Sangiorgi G.

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Abstract

BACKGROUND: Despite the availability of several potent antithrombotic agents, the optimal antiplatelet regimen in elective patients undergoing complex percutaneous coronary interventions is still debated. Aim of the INtegrilin plus STenting to Avoid myocardial Necrosis Trial will be to assess the safety and efficacy of routine usage of the glycoprotein IIb/IIIa inhibitor eptifibatide in patients already treated with aspirin and clopidogrel and undergoing implantation of at least two drug-eluting stents in the same lesion, thus identifying a clinically stable but anatomically complex patient subset. DESIGN: This will be a single-blind, placebo-controlled multicenter randomized trial. METHODS: Patients with stable coronary artery disease, who are undergoing percutaneous coronary intervention by means of implantation of greater than 33 mm of drug-eluting stents (e.g. with two 23-mm drug-eluting stents or one 32-mm and one 12-mm drug-eluting stent), will be randomized, after administration of aspirin and clopidogrel (600 mg loading dose recommended), to eptifibatide and unfractioned heparin according to the ESPRIT protocol or placebo and unfractioned heparin. Blood draws for creatine kinase-MB mass, total creatine kinase, and cardiac troponin levels will be taken at baseline, 6 and 12 h postprocedurally. Patients will be followed for clinical events by direct visit or phone contact up to 6 months. The primary endpoint of the study will be the rate of abnormal values of creatine kinase-MB mass after percutaneous coronary intervention. Secondary endpoints will be the composite of cardiac death, nonfatal myocardial infarction, urgent target vessel revascularization, and thrombotic bailout glycoprotein IIb/IIIa inhibitor therapy within 180 days, and in-hospital, 1-month and 6-month major adverse cardiovascular events, defined as the composite of cardiac death, nonfatal myocardial infarction or urgent target vessel revascularization. IMPLICATIONS: The INtegrilin plus STenting to Avoid myocardial Necrosis Trial study will test for the first time the beneficial impact of routine glycoprotein IIb/IIIa inhibition on top of dual oral antiplatelet

treatment in clinically stable yet anatomically complex patients undergoing drug-eluting stents implantation. Results of this single-blind randomized trial will provide important insights to improve the management strategy of patients and outcomes in the current drug-eluting stents era.

44.

J Invasive Cardiol. 2008 Aug;20(8):411-6.

Two-year intravascular ultrasound observations in diabetic patients treated with single and double dose sirolimus-eluting stents: results of the double dose diabetes (3D) study.

Hur SH, Ako J, Shimada Y, Tsujino I, Hassan AH, Abizaid A, Shiran A, Lewis BS, Guagliumi G, Cohen SA, Honda Y, Fitzgerald PJ, Sousa JE.

Center for Cardiovascular Technologies, Stanford University Medical Center, Stanford, CA 94305-563, USA.

Abstract

BACKGROUND: Diabetes has been reported as an independent predictor of restenosis after drug-eluting stent implantation. The purpose of this study was to assess the long-term impact of increased drug dose in sirolimus-eluting stents (SES) on neointimal hyperplasia (NIH) in diabetic patients using volumetric intravascular ultrasound analysis. METHODS: The 3D trial is a multicenter, prospective, randomized, feasibility study of double-dose (280 microg/cm2) or conventional single-dose (140 microg/cm2) SES for the treatment of de novo coronary lesions in diabetic patients. To evaluate long-term efficacy, complete serial volumetric analyses (baseline, 6-month and 2-year follow up) were performed in 39 diabetic patients (17 single-dose, 22 double-dose). Each volume was divided by stent length to acquire volume index, expressed as mm3/mm. Percent neointimal volume was calculated as (neointimal volume/stent volume) x 100 at follow up. RESULTS: Volumetric analysis showed similar results over time between the 2 stent groups ($p = NS$ for all). At 2-year follow up, minimal increases in NIH area and percent NIH were observed in both groups, which translated into a decrease in lumen volume index compared to baseline ($p < 0.05$ for all). No late-acquired incomplete stent apposition was observed in either group. CONCLUSIONS: The current single dose of sirolimus in SES is effective in inhibiting NIH in diabetic patients up to 2 years. In this patient subset, double-dose SES did not confer additional NIH suppression at 2-year follow up compared to conventional single-dose SES.

PMID: 18688066 [PubMed - indexed for MEDLINE]Free Article

Related citations

45.

Am J Cardiol. 2008 Aug 15;102(4):401-3. Epub 2008 May 28.

Comparison of higher clopidogrel loading and maintenance dose to standard dose on platelet function and outcomes after percutaneous coronary intervention using drug-eluting stents.

Abuzahra M, Pillai M, Caldera A, Hartley WB, Gonzalez R, Bobek J, Dokainish H, Lakkis N.

Department of Medicine, Baylor College of Medicine, Houston, Texas, USA.

Abstract

Adequate antiplatelet therapy is paramount for good clinical outcomes in patients undergoing percutaneous coronary intervention (PCI). The purpose of this study was to determine whether a high-dose regimen of clopidogrel in patients undergoing PCI is superior to standard dosing. A total of 119 patients undergoing PCI were blindly randomized in 2:1 fashion to receive clopidogrel loading 600 mg on the table immediately before PCI and 75 mg 2 times/day for 1 month (high-dose group) versus standard dosing (300 mg loading and 75 mg/day; low-dose group). Platelet aggregation was measured using light transmission aggregometry at baseline, 4 hours, and 30 days. The composite of cardiovascular death, myocardial infarction, and target vessel revascularization was studied at 30 days in addition to major and minor bleeding. Baseline characteristics and baseline platelet aggregation were similar in the 2 groups. Percent inhibitions of platelet activity were 41% and 27% in the high-dose group versus 19% and 10% in the low-dose group at 4 hours and 30 days ($p = 0.046$ and 0.047, respectively). Composite clinical end points were 10.3% in the high-dose group and 23.8% in the low-dose group ($p = 0.04$). No difference was noted in major or minor bleeding. In conclusion, a higher loading and maintenance dose of clopidogrel in patients undergoing PCI results in superior platelet inhibition and decreased cardiovascular events without increasing bleeding complications.

PMID: 18678295 [PubMed - indexed for MEDLINE]

Related citations

ELSEVIER FULL-TEXT ARTICLE

46.

Am J Cardiol. 2008 Aug 1;102(3):304-10. Epub 2008 May 14.

Intravascular ultrasound evaluation of optimal drug-eluting stent expansion after poststent balloon dilation using a noncompliant balloon versus a semicompliant balloon (from the Poststent Optimal Stent Expansion Trial [POET]).

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Division of Cardiology, Cardiovascular Center, Yonsei University College of Medicine, Seoul, Korea.

Comment in:

- Am J Cardiol. 2008 Oct 15;102(8):1113-4.

Abstract

The impact of type of balloon such as noncompliant (NC; Quantum) or semicompliant (SC; Maverick(2)) used after stent dilation on optimal stent expansion (OSE) has not been established for drug-eluting stents (DESs). We conducted a prospective multicenter, randomized study to compare NC with SC balloons after stent balloon dilatation. A total of 301 patients (127 men, 83 women, 62 +/- 9 years of age) treated with a DES (sirolimus-eluting stent [SES], n = 152; paclitaxel-eluting stent, n = 149) were included. OSE followed the definition of the Multicenter Ultrasound Stenting in Coronaries (MUSIC) study. The primary end point was the incidence of OSE using intravascular ultrasound according to type of balloon. Baseline characteristics of each group showed no significant differences. OSE in the SC balloon group was achieved at higher rates than the NC balloon group (53 +/- 35%, vs 73 +/- 48%, p = 0.022 in all stents; 25 +/- 33%, vs 36, 48%, p = 0.051 in SESs). However, any differences in the achievement of OSE between the NC and SC balloon groups were not present in paclitaxel-eluting stents. In conclusion, despite postadjuvant balloon inflations with high pressures, underexpansion of the DES was seen commonly. Between the 2 types of balloon for adjuvant dilation after DES implantation, same-size SC balloons could be more useful for obtaining OSE than NC balloons, especially in SESs.

PMID: 18638591 [PubMed - indexed for MEDLINE]

Related citations

47.

Minerva Cardioangiol. 2008 Aug;56(4):381-6.

Temporal trends in baseline characteristics and peri-procedural complications of percutaneous drug-eluting stent implantation for unprotected left main disease: a single high-volume center experience.

Sheiban C, Moretti C, La Spina C, Sillano D, Garrone P, Lombardi P, Sciuto F, Omedè P, Biondi-Zoccai G, Trevi GP.

Interventional Cardiology, Division of Cardiology University of Turin, Turin, Italy.

Abstract

AIM: Percutaneous drug-eluting stent (DES) implantation is commonly used in patients with unprotected left main (ULM) disease. As this procedure has been performed routinely in Turin Center since 2002, this article aimed to summarize a five year-experience in DES implantation in the ULM. METHODS: Baseline, procedural and in-hospital outcome data of all patients with ULM undergoing percutaneous coronary intervention (PCI) with DES between July 2002 and October 2006 at Turin Center have been collected. Patients were randomized into four groups: A (patients treated between July 2002 and December 2003), B (treated in 2004), C (treated in 2005) and D (treated in 2006). The baseline surgical risk features was to be compared with the European System for Cardiac Operative Risk Evaluation, disease location in the ULM, and in-hospital major adverse cerebro-cardiovascular events (MACCE), defined as death, myocardial infarction, repeat percutaneous revascularization, coronary artery bypass grafting, stroke, or stent thrombosis. RESULTS: Out of a total of 4 432 coronary interventional procedures 198 patients treated with DES in the ULM were identified. There was a significant increase in the number of patients treated (P=0.00095), but no difference in EuroSCORE across groups (P=0.14). Conversely, there was a significant temporal trend in the incidence of bifurcational ULM being treated with DES (P=0.03). Intriguingly, despite this increase in adverse lesion characteristics, no

significant increase was found in the rate of in-hospital MACCE (P=0.93). CONCLUSION: In this single-center study, the number of patients being treated with DES for ULM disease has risen across the years, although keeping a similar surgical risk profile. Distal ULM involvement is no longer considered an absolute contraindication to PCI, as testified by the increasing frequency of such lesion among patients undergoing DES implantation at this Institution, with remarkably low rates of adverse events.

PMID: 18614981 [PubMed - indexed for MEDLINE]

Related citations

48.

Eur J Cardiothorac Surg. 2008 Aug;34(2):376-82; discussion 382-3. Epub 2008 Jun 25.

Frequency and pattern of de-novo three-vessel and left main coronary artery disease; insights from single center enrolment in the SYNTAX study.

Rastan AJ, Boudriot E, Falk V, Kappetein AP, Borger MA, Serruys PW, Schuler G, Mohr FW.

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Abstract

OBJECTIVES: To characterize the current patient population regarding extent and pattern of coronary artery disease (CAD) in a routine cardiac catheterization practice with special focus on de-novo three-vessel coronary artery and/or left main disease (3-VD/LM) during enrolment in the SYNTAX study (synergy between PCI with Taxus drug-eluting stent and cardiac surgery) comparing percutaneous coronary intervention (PCI) with drug-eluting stents (DES) and coronary artery bypass grafting (CABG) in 3-VD/LM. METHODS: During a 4-month study enrolment period, a total of 3319 consecutive adult patients undergoing coronary angiography were prospectively recorded. Patients with de-novo 3-VD/LM were screened in the daily heart team conference by interventional cardiologists and cardiac surgeons concerning suitability for study enrolment. Complexity of CAD was quantified by the SYNTAX score. RESULTS: A total of 694 patients (20.9%) presented with 3-VD/LM, of which 271 had previous CABG and 232 previous PCI treatment. Of the 191 patients with de-novo 3-VD/LM, SYNTAX study exclusion

criteria were present in 87 patients consisting mostly of acute myocardial infarction (n=47) or concomitant indications for additional heart surgery (n=35). A total of 104 patients (54.4% of all screened) were potentially suitable for study enrolment. Of these, 13 patients refused study participation, 10 presented with uncertain protocol adherence and 6 were already participating in other cardiovascular trials. A total of 67 patients were therefore enrolled in the SYNTAX study, representing 9.7% of 3-VD/LM and 35.1% of all screened patients. Twenty-four patients were not amenable for PCI and were therefore assigned to the CABG registry. Compared to the randomized cohort, these patients had more complex CAD (SYNTAX score 34 vs 26, p=0.003) with significantly more chronic coronary vessel occlusion (70.8% vs 22.5%, p=0.04). In the randomized cohort, CABG and PCI patients were comparable in age (PCI 69.7 years vs CABG 67.2 years), additive EuroSCORE (4.8 vs 4.4), EF (57.8% vs 52.4%), number of coronary lesions (4.5 vs 4.6), left main disease (42.9% vs 52.6%) and coronary vessel occlusion. CONCLUSIONS: Patients with de-novo 3-VD/LM represented a small proportion of patients undergoing coronary angiography at our center. However, SYNTAX study inclusion and randomization rates of these screened patients were high. Chronic vessel occlusion and high SYNTAX scores were more common in CABG registry patients compared to randomized patients.

PMID: 18579392 [PubMed - indexed for MEDLINE]Free Article

49.

Int J Cardiol. 2009 May 29;134(3):351-5. Epub 2008 Jun 24.

The clopidogrel resistance can be attenuated with triple antiplatelet therapy in patients undergoing drug-eluting stents implantation.

Shim CY, Yoon SJ, Park S, Kim JS, Choi JR, Ko YG, Choi D, Ha JW, Jang Y, Chung N, Shim WH, Cho SY.

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Abstract

BACKGROUND: Triple antiplatelet therapy may have a beneficial effect on prevention of thrombotic complication in patients undergoing coronary stenting. We investigated the prevalence of aspirin and clopidogrel resistance in patients treated with dual and triple antiplatelet regimen after percutaneous coronary intervention (PCI) with drug-eluting stents (DES). METHODS: A total of 400 consecutive

patients underwent successful PCI with DES were randomly assigned to therapy with dual antiplatelet regimens (aspirin plus clopidogrel, Group I, n = 200) and triple antiplatelet regimens (aspirin plus clopidogrel plus cilostazol, Group II, n = 200) At two weeks after PCI, aspirin and clopidogrel resistance were assayed in 379 patients (Group I, n = 186; Group II, n = 193) by using the VerifyNow System. RESULTS: In Group I, 21 (11.3%) patients had aspirin resistance and 74 (40.0%) had clopidogrel resistance. In Group II, 19 (9.8%) were resistant to aspirin and 38 (19.7%) to clopidogrel. The aspirin reaction unit (ARU) was not significantly different between groups (448+/-67 vs. 439+/-64, P = 0.200), but the percent inhibition of clopidogrel was higher in Group II (41.4+/-24.3%,) comparing with that of Group I (26.5+/-18.7%, P < 0.001). CONCLUSION: With triple antiplatelet therapy, the prevalence of clopidogrel resistance can be attenuated in patients undergoing PCI with DES.

PMID: 18579227 [PubMed - indexed for MEDLINE]

50.

Am J Cardiol. 2008 Jul 1;102(1):19-26. Epub 2008 May 9.

Intravascular ultrasound assessment of expansion of the sirolimus-eluting (cypher select) and paclitaxel-eluting (Taxus Express-2) stent in patients with diabetes mellitus.

Jensen LO, Maeng M, Mintz GS, Christiansen EH, Hansen KN, Galloe A, Kelbaek H, Hansen HS, Joergensen E, Lassen JF, Thuesen L, Thayssen P.

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Abstract

Patients with diabetes have a higher risk for in-stent restenosis after coronary stent implantation. Drug-eluting stents (DES) are highly effective in reducing in-stent restenosis. Once neointimal hyperplasia is suppressed with DES, the impact of stent underexpansion becomes magnified. The aim of this study was to evaluate DES expansion in patients with diabetes. Ninety-five patients with diabetes were randomized to Cypher Select (n = 48) or Taxus Express-2 (n = 47) stent implantation. Intravascular ultrasound was performed after stent implantation. Stent expansion was defined as the ratio of measured to predicted minimum stent diameter. There was a trend for lower stent expansion in the

Cypher Select stent group (0.74 +/- 0.08 vs 0.78 +/- 0.11 in the Taxus Express-2 stent group, p = 0.061). Cypher Select stents achieved a final minimal stent cross-sectional area of 5.5 +/- 1. 8 mm2, compared with 6.4 +/- 1.9 mm2 for Taxus Express-2 stents (p = 0.015). For stents with nominal diameters > or =2.75 mm (Cypher Select n = 40, Taxus Express-2 n = 38), 42.5% of the Cypher Select stents and 10.5% of the Taxus Express-2 stents did not achieve a final minimum stent area of 5 mm2 (p = 0.002). Insulin treatment (relative risk 0.31, 95% confidence interval 0.10 to 0.95, p = 0.041) and stent type (relative risk 0.15, 95% CI 0.04 to 0.53, p = 0.003) were independent predictors of not achieving a minimum stent area >5.0 mm2. In conclusion, an important percentage of DES in patients with diabetes fail to achieve the manufacturers' predicted final minimal stent diameter. Cypher Select stent and insulin treatment were independent predictors of not achieving a minimum stent area >5.0 mm2.

PMID: 18572030 [PubMed - indexed for MEDLINE]

51.

J Am Coll Cardiol. 2008 Jun 24;51(25):2385-95.

Clinical efficacy of drug-eluting stents in diabetic patients: a meta-analysis.

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Abstract

OBJECTIVES: The purpose of this study was to compare estimates for revascularization and major adverse cardiac events (MACE) (death, myocardial infarction, repeat revascularization) in diabetic patients treated with paclitaxel- and sirolimus-eluting stents (PES and SES). BACKGROUND: Outcomes in diabetic patients treated with PES and SES have not been adequately evaluated. METHODS: We searched MEDLINE/EMBASE from January 2002 to February 2007 and identified abstracts/presentations from this period at major cardiology conferences. Randomized controlled trials (RCTs) and registries were included if data for diabetic patients treated with PES or SES were available. Point estimates with 95% confidence intervals (CIs) were computed as summary statistics. RESULTS: In RCTs (13 trials; n = 2,422) similar point estimates for target lesion revascularization (TLR) (PES:

8.6%, 95% CI 6.5% to 11.3%; SES: 7.6%, 95% CI 5.8% to 9.9%) and MACE (PES: 15.4%, 95% CI 12.4% to 19.1%; SES: 12.9%, 95% CI 8.5% to 19.2%) were observed. In head-to-head trials (4 RCTs), no difference in the likelihood of TLR (PES vs. SES) was observed (odds ratio [OR] 1.37, 95% CI 0.64 to 2.9, p = 0.42). In registries (16 registries; n = 10,156), point estimates for target vessel revascularization (TVR) (PES: 5.8%, 95% CI 3.9% to 8.5%; SES: 7.2%, 95% CI 4.6% to 11.2%) and MACE (PES: 10.1%, 95% CI 7.3% to 13.8%; SES: 11.9%, 95% CI 8.6% to 16.4%) were also similar. In registries reporting outcomes with both stents (8 registries for TVR and 7 registries for MACE), the likelihood of TVR (PES vs. SES) (OR 0.77, 95% CI 0.54 to 1.10, p = 0.15) and MACE (OR 0.83, 95% CI 0.68 to 1.01, p = 0.056) were nonsignificantly lower with PES. CONCLUSIONS: This analysis of over 11,000 diabetic patients treated with drug-eluting stents demonstrates single-digit revascularization rates. Furthermore, revascularization and MACE estimates are similar with both PES and SES.

PMID: 18565394 [PubMed - indexed for MEDLINE]

52.

Am J Cardiol. 2008 Jun 15;101(12):1704-11. Epub 2008 Apr 9.

Impact of stent deployment procedural factors on long-term effectiveness and safety of sirolimus-eluting stents (final results of the multicenter prospective STLLR trial).

Costa MA, Angiolillo DJ, Tannenbaum M, Driesman M, Chu A, Patterson J, Kuehl W, Battaglia J, Dabbons S, Shamoon F, Flieshman B, Niederman A, Bass TA; STLLR Investigators.

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Comment in:

- Am J Cardiol. 2008 Oct 1;102(7):954.

Abstract

Drug-eluting stent failures were associated with various clinical factors. However, the clinical impact of stent deployment technique was unknown. This study was designed to evaluate the frequency and

impact of suboptimal percutaneous coronary intervention on long-term outcomes of 1,557 patients treated with sirolimus-eluting stents (SESs) in 41 US hospitals. All steps of the interventional procedure were scrutinized by an independent core laboratory to determine the occurrence of geographic miss (GM). GM included longitudinal (LGM; injured or diseased segment not covered by SES) or axial GM (balloon-artery size ratio <0.9 or >1.3) mismatches. Patients with and without GM were stratified (GM vs no-GM group). Patients, investigators, and the independent clinical event adjudication committee were blind to study group assignments. The primary end point was 1-year target-vessel revascularization (TVR) rate. Incidences and predictors of GM and safety outcomes were secondary end points. GM occurred in 943 patients (66.5%): 47.6% had LGM, 35.2% had axial GM, and 16.5% had both. One-year TVR rates were 5.1% in the GM group versus 2.5% in the no-GM group (p=0.025). TVR was 6.1% in the LGM versus 2.6% in the no-LGM subgroups (p=0.001). The association of GM with 1-year TVR was independent of clinical or anatomic factors (hazard ratio 2.0, 95% confidence interval 1.0 to 4.02, p=0.05). There was a 3-fold increase in myocardial infarction rates associated with GM (2.4% vs 0.8%; p=0.04). In conclusion, GM occurred frequently during SES implantation and was associated with increased risk of TVR and myocardial infarction at 1 year. These results emphasized the need for improvement in contemporary percutaneous coronary intervention practices and technologies.

53.

Clin Res Cardiol. 2008 Oct;97(10):773-81. Epub 2008 Jun 5.

Two year follow-up after treatment of coronary in-stent restenosis with a paclitaxel-coated balloon catheter.

Scheller B, Hehrlein C, Bocksch W, Rutsch W, Haghi D, Dietz U, Böhm M, Speck U.

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Abstract

BACKGROUND: We are presenting an extension of a previously published trial on the efficacy and safety of a paclitaxel-coated balloon in coronary ISR in a larger patient population and after a complete follow-up of 2 years. METHODS: Hundred eight patients were enrolled in two separately randomized, double-blind multicenter trials on efficacy and safety using an identical protocol. Patients were treated by

the paclitaxel-coated (3 microg/mm(2) balloon surface; Paccocath) or an uncoated balloon. The main inclusion criteria were a diameter stenosis of >or=70% and <30 mm length with a vessel diameter of 2.5-3.5 mm. The primary endpoint was angiographic late lumen loss in-segment. Secondary endpoints included binary restenosis rate and major adverse cardiovascular events (MACE). RESULTS: Quantitative coronary angiography revealed no differences in baseline parameters. After six months in-segment late lumen loss was 0.81 +/- 0.79 mm in the uncoated balloon group vs. 0.11 +/- 0.45 mm (P < 0.001) in the drug-coated balloon group resulting in a binary restenosis rate of 25/49 vs. 3/47 (P < 0.001). Until 12 months post procedure 20 patients in the uncoated balloon group compared to two patients in the coated balloon group required target lesion revascularization (P = 0.001). Between 12 and 24 only two MACE were recorded, a stroke in the uncoated and a target lesion revascularization in the coated balloon group. CONCLUSION: Treatment of coronary ISR with paclitaxel-coated balloon catheters persistently reduces repeat restenosis up to 2 years. (ClinicalTrials.gov Identifier: NCT00106587, NCT00409981).

PMID: 18536865 [PubMed - indexed for MEDLINE]

54.

Int J Cardiol. 2009 Apr 17;133(3):354-8. Epub 2008 Jun 3.

Incidence and predictors of drug-eluting stent fractures in long coronary disease.

Kim HS, Kim YH, Lee SW, Park DW, Lee CW, Hong MK, Park SW, Ko JK, Park JH, Lee JH, Choi SW, Seong IW, Cho YH, Lee NH, Kim JH, Chun KJ, Park SJ; Long-DES-II study investigators.

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Abstract

BACKGROUND: Stent fractures after drug-eluting stent (DES) implantation have not been evaluated sufficiently in patients with long coronary artery disease. METHODS: This study comprised of 415 patients, who were enrolled in the Long-DES-II study and had a complete serial angiography both before and after procedure and also at follow-up. The lesions were > or =25 mm in length and were randomly treated with sirolimus-eluting stents (SES, 210 lesions) or paclitaxel-eluting stent (205 lesions). RESULTS: DES fracture was identified in 7 lesions (1.7%): 1 minor, 3 moderate, and 3 severe

fractures. Most of the fractures occurred in patients who received SES (85.7%) and in the right coronary artery (RCA) lesions (71.4%). Lesions with fracture had a smaller minimal lumen diameter before procedure than lesions without fracture (0.38+/-0.55 vs. 0.71+/-0.46 mm, p=0.043). However, acute gain (2.28+/-0.39 vs. 1.44+/-0.60 mm, p=0.001) and late loss (0.81+/-0.49 vs. 0.42+/-0.50 mm, p=0.033) in analysis segment were greater in lesions with fracture. By multivariate analysis, the independent predictor of fracture was the RCA lesion (Odds ratio, 7.81; 95% CI, 1.45 approximately 42.04; p=0.017). Although one patient had an intermediate angiographic narrowing at the fracture site, there was no adverse cardiac event related with fracture. CONCLUSIONS: The incidence of stent fracture in long DES implantation was not common and was associated with SES implantation or RCA lesions. Fortunately, the clinical prognosis of DES fracture was somewhat benign.

PMID: 18508140 [PubMed - indexed for MEDLINE]

55.

Catheter Cardiovasc Interv. 2008 Jun 1;71(7):896-906.

Impact of platelet glycoprotein IIb/IIIa receptor inhibitors on outcomes of diabetic patients undergoing percutaneous coronary interventions using sirolimus-eluting stents.

Nikolsky E, Holmes DR, Mehran R, Dangas G, Schampaert E, Morice MC, Schofer J, Sousa JE, Fahy M, Na Y, Donohoe DJ, Moses JW, Leon MB.

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Comment in:

- Catheter Cardiovasc Interv. 2008 Jun 1;71(7):907-8.

Abstract

OBJECTIVE: We assessed the outcomes in diabetic patients undergoing percutaneous coronary intervention (PCI) using sirolimus-eluting stents (SES) as a function of treatment with glycoprotein (GP) IIb/IIIa inhibitors. METHODS AND RESULTS: Of 551 diabetic patients treated with a SES in nine trials (RAVEL, SIRIUS, E-SIRIUS, C-SIRIUS, REALITY, SVELTE, DIRECT, SIRIUS 2.25, and SIRIUS 4.0),

187 patients (33.9%) were administered GP IIb/IIIa inhibitors during PCI. GP IIb/IIIa blockade was associated with lower rates of myocardial infarction (MI) at 30 days (1.1% vs. 3.3%, P = 0.12) and at 1 year (1.1% vs. 4.7%, P = 0.04), and composite endpoint of cardiac death/MI at 1 year (2.2% vs. 6.2%, P = 0.05). Benefit from GP IIb/IIIa inhibitors was confined to 128 insulin-treated diabetics who had remarkable reduction in MI (0.0% vs. 6.3%, P = 0.04) and cardiac death/MI at 30 days (0.0% vs. 7.6%, P = 0.05) and at 1-year (0.0% vs. 13.4%, P = 0.01 and 0.0% vs. 15.7%, P = 0.0005, respectively). When treated with GP IIb/IIIa inhibitors, insulin-requiring diabetics had similar rates of 1-year death/MI when compared with the nondiabetic patients (0% vs. 4.7%, P = 0.13, respectively). There were no significant differences in outcomes as a function of GP IIb/IIIa blockade in diabetics not treated with insulin. CONCLUSION: In this analysis, outcomes of insulin requiring diabetic patients undergoing PCI with SES were considerably improved with adjunctive GP IIb/IIIa inhibitors by decreasing the rates of MI and composite endpoint of cardiac death/MI. 2008 Wiley-Liss, Inc.

PMID: 18498145 [PubMed - indexed for MEDLINE]

56.

Eur J Clin Invest. 2008 Jun;38(6):361-71.

Study comparing the double kissing (DK) crush with classical crush for the treatment of coronary bifurcation lesions: the DKCRUSH-1 Bifurcation Study with drug-eluting stents.

Chen SL, Zhang JJ, Ye F, Chen YD, Patel T, Kawajiri K, Lee M, Kwan TW, Mintz G, Tan HC.

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Abstract

BACKGROUND: Classical crush has a lower rate of final kissing balloon inflation (FKBI) immediately after percutaneous coronary intervention (PCI). The double kissing (DK) crush technique has the potential to increase the FKBI rate, and no prospective studies on the comparison of classical with DK crush techniques have been reported. MATERIALS AND METHODS: Three hundred and eleven patients with true bifurcation lesions were randomly divided into classical (n = 156) and DK crush (n = 155) groups. Clinical and angiographic details at follow-up at 8 months were indexed. The primary end

point was major adverse cardiac events (MACE) including myocardial infarction, cardiac death and target lesion revascularization (TLR) at 8 months. RESULTS: FKBI was 76% in the classical crush group and 100% in the DK group (P < 0.001). The incidence of stent thrombosis was 3.2% in the classical crush group (5.1% in without- and 1.7% in with-FKBI) and 1.3% in the DK crush group. Cumulative 8 month MACE was 24.4% in the classical crush group and 11.4% in the DK crush group (P = 0.02). The TLR-free survival rate was 75.4% in the classical crush group and 89.5% in the DK crush group (P = 0.002). CONCLUSIONS: DK crush technique has the potential of increasing FKBI rate and reducing stent thrombosis, with a further reduction of TLR and cumulative MACE rate at 8 months.

PMID: 18489398 [PubMed - indexed for MEDLINE]PMCID: PMC2439595Free PMC Article

57.

Coron Artery Dis. 2008 May;19(3):211-5.

The efficacy of adjunctive balloon postdilation at the overlapping site of drug-eluting stent in diffuse long coronary lesion.

Suh SY, Rha SW, Na JO, Choi CU, Kim JW, Kim EJ, Park CG, Seo HS, Oh DJ.

Cardiovascular Center, Korea University Guro Hospital, Seoul, Korea.

Abstract

BACKGROUND: Data regarding the efficacy of adjunctive balloon postdilation (ABP) at the site of two or more overlapping drug-eluting stent (DES) implantation in diffuse long lesion angioplasty are limited. This study was aimed to evaluate the efficacy of routine ABP to the overlapping DES sites in terms of clinical and angiographic outcomes. METHODS: We enrolled 88 patients (55 men, mean age 63.51+/-10.24 years), and 93 lesions with diffuse long lesion were treated with DES. The clinical and angiographic outcomes up to 6 months of 35 patients in the without routine ABP group were compared with those of 53 patients in the with ABP group. RESULTS: Baseline clinical characteristics, procedural characteristics, angiographic lesion length, lesion type and DES type were similar between the two groups. Late loss and binary restenosis at 6 months were similar between the two groups. The death, Q-wave myocardial infarction and the major adverse cardiac events were similar between the two groups (7.9 vs. 9.1% in ABP group, P=NS), but there was a trend toward lesser target lesion and vessel revascularization in no ABP group (2.6 vs. 9.0% in no ABP group, P=0.09). CONCLUSION: The routine

ABP at the overlapping site of DES implantations in a diffuse long coronary lesion showed no significant benefits in terms of angiographic and clinical outcomes compared with those of patients without routine ABP.

PMID: 18418239 [PubMed - indexed for MEDLINE]

58.

J Am Coll Cardiol. 2008 Mar 4;51(9):899-905.

Randomized comparison of distal protection versus conventional treatment in primary percutaneous coronary intervention: the drug elution and distal protection in ST-elevation myocardial infarction (DEDICATION) trial.

Kelbaek H, Terkelsen CJ, Helqvist S, Lassen JF, Clemmensen P, Kløvgaard L, Kaltoft A, Engstrøm T, Bøtker HE, Saunamäki K, Krusell LR, Jørgensen E, Hansen HH, Christiansen EH, Ravkilde J, Køber L, Kofoed KF, Thuesen L.

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Abstract

OBJECTIVES: The purpose of this study was to evaluate the use of distal protection during percutaneous coronary intervention (PCI) for ST-segment elevation myocardial infarction (STEMI) in native coronary vessels. BACKGROUND: Embolization of material from the infarct-related lesion during PCI may result in impaired myocardial perfusion and worsen the prognosis. Previous attempts to protect the microcirculation during primary PCI have had conflicting results. METHODS: We randomly assigned 626 patients with STEMI referred within 12 h to have PCI performed with (n = 312) or without (n = 314) distal protection. The primary end point was complete (>or=70%) ST-segment resolution detected by continuous ST-segment monitoring. Blood levels of troponin-T and creatine kinase-MB were monitored before and after the procedure, and echocardiographic determination of the left ventricular wall motion index (WMI) was performed before discharge. RESULTS: Patients were well matched in terms of demographic and angiographic baseline characteristics. There was no significant difference in the occurrence of the primary end point (76% vs. 72%, p = 0.29), no difference in maximum troponin-T (4.8

microg/l and 5.0 microg/l, p = 0.87) or maximum creatine kinase-MB (185 microg/l and 184 microg/l, p = 0.99), and no difference in median WMI (1.70 vs. 1.70, p = 0.35). The rate of major adverse cardiac and cerebral events (MACCE) 1 month after PCI was 5.4% with distal protection and 3.2% with conventional treatment (p = 0.17). CONCLUSIONS: The routine use of distal protection by a filterwire system during primary PCI does not seem to improve microvascular perfusion, limit infarct size, or reduce the occurrence of MACCE.

PMID: 18308157 [PubMed - indexed for MEDLINE]

Related citations

59.

Eur Heart J. 2008 Mar;29(5):673-9. Epub 2008 Feb 19.

Impact of previous percutaneous transluminal coronary angioplasty and/or stenting revascularization on outcomes after surgical revascularization: insights from the imagine study.

Chocron S, Baillot R, Rouleau JL, Warnica WJ, Block P, Johnstone D, Myers MG, Calciu CD, Nozza A, Martineau P, van Gilst WH; IMAGINE Investigators.

Department of Cardiac Surgery, Hopital Jean Minjoz, University of Franche-Comté, 25030 Besançon Cedex, France. sidney.chocron@univ-fcomte.fr

Comment in:

- Eur Heart J. 2008 Mar;29(5):573-5.

Abstract

AIM: To determine the impact of previous coronary artery revascularization by percutaneous transluminal coronary angioplasty and/or stenting (PCI) on outcome after subsequent coronary artery bypass grafting (CABG). METHODS AND RESULTS: The ischaemia management with Accupril post-bypass Graft via Inhibition of the coNverting Enzyme (IMAGINE) trial, conducted between November 1999 and September 2004, tested whether early initiation of an angiotensin-converting enzyme inhibitor post-CABG, in stable patients with LVEF >or=40%, would reduce cardiovascular events. Of the 2489

patients included in the IMAGINE trial, undergoing their first operation, 430 had a history of PCI prior to surgery (PCI group), and 2059 were referred to surgery without previous PCI (non-PCI group). There was a significant increase in the primary IMAGINE endpoint in the PCI group, HR = 1.53 [1.17-1.98], P = 0.0016. Coronary revascularization, HR = 1.80 [1.13-2.87], P = 0.014, unstable angina requiring hospitalization, HR = 2.43 [1.52-3.89], P = 0.0002, were the two individual components that significantly increased in the PCI group, even when adjusted for baseline characteristics (age, sex, history of myocardial infarction or stroke, diabetes, treatment group, or off-pump surgery). CONCLUSION: Patients with left ventricular ejection fraction >or=40% having a history of PCI prior to surgery had a worse outcome post-CABG than those with no prior PCI. Further studies are needed to investigate whether these results apply for drug eluting stents.

PMID: 18285358 [PubMed - indexed for MEDLINE]Free Article

Related citations

60.

N Engl J Med. 2008 Feb 14;358(7):689-99.

Local delivery of paclitaxel to inhibit restenosis during angioplasty of the leg.

Tepe G, Zeller T, Albrecht T, Heller S, Schwarzwälder U, Beregi JP, Claussen CD, Oldenburg A, Scheller B, Speck U.

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Comment in:

- N Engl J Med. 2008 May 29;358(22):2406-7; author reply 2407.
- N Engl J Med. 2008 May 29;358(22):2406; author reply 2407.

Abstract

BACKGROUND: Drug-eluting stents reduce restenosis in coronary arteries, but clinical trials have failed to prove their efficacy in peripheral arteries. We investigated the use of paclitaxel-coated angioplasty

balloons and paclitaxel dissolved in the angiographic contrast medium during angioplasty of the leg. METHODS: In a small, multicenter trial, we randomly assigned 154 patients with stenosis or occlusion of a femoropopliteal artery to treatment with standard balloon catheters coated with paclitaxel, uncoated balloons with paclitaxel dissolved in the contrast medium, or uncoated balloons without paclitaxel (control). The primary end point was late lumen loss at 6 months. RESULTS: The mean (+/-SD) age of the patients was 68+/-8 years, 24% were smokers, and 49% had diabetes. Twenty-seven percent of the lesions were total occlusions, and 36% were restenotic lesions. The mean lesion length was 7.4+/-6.5 cm. There were no significant differences in baseline characteristics between the groups. There were no adverse events attributable to the paclitaxel-coated balloons. At 6 months, the mean late lumen loss was 1.7+/-1.8 mm in the control group, as compared with 0.4+/-1.2 mm (P<0.001) in the group treated with paclitaxel-coated balloons and 2.2+/-1.6 mm (P=0.11) in the group treated with paclitaxel in the contrast medium. The rate of revascularization of target lesions at 6 months was 20 of 54 (37%) in the control group, 2 of 48 (4%) in the group treated with paclitaxel-coated balloons (P<0.001 vs. control), and 15 of 52 (29%) in the group treated with paclitaxel in the contrast medium (P=0.41 vs. control); at 24 months, the rates increased to 28 of 54 (52%), 7 of 48 (15%), and 21 of 52 (40%), respectively. CONCLUSIONS: Use of paclitaxel-coated angioplasty balloons during percutaneous treatment of femoropopliteal disease is associated with significant reductions in late lumen loss and target-lesion revascularization. No significant benefit is seen with the use of a paclitaxel-containing contrast medium. (ClinicalTrials.gov number, NCT00156624 [ClinicalTrials.gov].).

PMID: 18272892 [PubMed - indexed for MEDLINE]Free Article

- 61.

Catheter Cardiovasc Interv. 2008 Feb 1;71(2):166-72.

Final kissing balloon inflation by classic crush stenting did not improve the clinical outcomes for the treatment of unprotected left main bifurcation lesions: the importance of double-kissing crush technique.

Chen S, Zhang J, Ye F, Chen Y, Fang W, Wei M, He B, Sun X, Yang S, Kwan TW.

Nanjing First Hospital, Nanjing Medical University, Jiang Su, China.

Comment in:

- Catheter Cardiovasc Interv. 2008 Feb 1;71(2):173-4.

Abstract

BACKGROUND: The mechanisms contributing to final kissing balloon inflation between classic crush and double-kissing (DK) crush stenting techniques for the treatment of coronary bifurcation lesions contrast. The authors compared the clinical outcomes in patients with unprotected distal left main bifurcation lesions treated by classic crush or DK crush stenting techniques. METHODS: Thirty-seven patients with unprotected left main bifurcation lesions were selected (20 in classic crush, 17 in DK crush groups) from a prospective, multicenter, randomized DKCRUSH-1 BIFURCATION STUDY. Clinical and angiographic data were analyzed. RESULTS: Follow-up was available for all patients. There were significant differences of the bifurcation angle between the classic and the DK crush group (83.28 +/- 20.69)(0) vs. (67.71 +/- 26.35)(0), P = 0.02). Unsatisfactory kissing rate in the classic group was significantly higher (26.32% vs. 5.88%, P = 0.01). The acute gain in the side branch was greater in the DK crush stent group (1.48 +/- 0.50 mm vs. 1.36 +/- 0.55 mm, P = 0.03). The accumulative restenosis rate in the main vessel segments, side branch, and accumulative MACE were higher in the classic group than the DK crush group (13.39% vs. 5.12%, P = 0.058, 42.10% vs. 5.88%, P = 0.01, 42.10% vs. 5.82%, P = 0.001, respectively). By logistic regression, acute gain in side branch immediately after PCI, bifurcation angle and unsatisfactory kissing were three independent factors of TLR at 8-month follow-up. CONCLUSION: Classic crush stenting with final kissing balloon inflations did not improve the clinical outcomes for the treatment of left main bifurcation lesion when compared with DK crush stenting technique.

PMID: 18231996 [PubMed - indexed for MEDLINE]

62.

Eur Heart J. 2005 Oct;26(20):2148-53. Epub 2005 Jun 23.

13-year follow-up of the German angioplasty bypass surgery investigation.

Kaehler J, Koester R, Billmann W, Schroeder C, Rupprecht HJ, Ischinger T, Jahns R, Vogt A, Lampen M, Hoffmann R, Riessen R, Berger J, Meinertz T, Hamm CW.

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Abstract

AIMS: The German Angioplasty Bypass Surgery Investigation was designed to compare symptomatic efficacy and safety of percutaneous coronary balloon angioplasty (PTCA) with coronary artery bypass surgery (CABG) in patients with symptomatic multi-vessel disease. This follow-up study was performed to determine the long-term outcome of patients following these interventions. METHODS AND RESULTS: From 1986 to 1991, 359 patients with angina CCS class II-IV, age below 75 years, and coronary multi-vessel disease requiring revascularization of at least two major coronary vessels were recruited at eight German centres and randomized to PTCA or CABG. From 337 patients undergoing the planned procedure, 324 patients could be followed-up (96%). Baseline parameters were identical in both groups, 2.2+/-0.6 vessels were treated in CABG patients, whereas 1.9+/-0.5 vessels were treated in PTCA patients. Thirty-seven per cent of surgical patients received internal mammary artery grafts, while no stents were used in patients undergoing PTCA. At the end of the 13-year follow-up period, the degree of angina, the degree of dyspnea, and the utilization of nitrates were comparable in both groups. With a total number of 76 deaths, Kaplan-Meier analysis revealed a comparable distribution in both groups. Although time to first re-intervention was significantly shorter in the PTCA group, P<0.001, frequencies of re-intervention (CABG, n=94; PTCA, n=136) and crossover rates (CABG to PTCA, n=49; PTCA to CABG, n=51) were comparable in both groups. CONCLUSION: The results of our 13-year follow-up suggest that in patients with symptomatic multi-vessel disease, both PTCA and CABG are associated with a comparable long-term survival and symptomatic efficacy. How far these results may be altered by developments such as drug-eluting stents or off-pump surgery remains to be determined.

PMID: 15975991 [PubMed - indexed for MEDLINE]Free Article

63.

Eur Heart J. 2005 Jul;26(13):1262-8. Epub 2005 Feb 28.

Drug-eluting stents compared with thin-strut bare stents for the reduction of restenosis: a prospective, randomized trial.

Pache J, Dibra A, Mehilli J, Dirschinger J, Schömig A, Kastrati A.

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Comment in:

- Eur Heart J. 2005 Aug;26(16):1686-7; author reply 1687.

Abstract

AIM: Drug-eluting stents have considerably reduced restenosis. Their relative merits have been assessed on the basis of comparisons made with control bare stents with thick struts. However, increased strut thickness negatively affects restenosis. No direct comparisons between drug-eluting stents and bare stents with thin struts have been performed. The aim of this study was to evaluate the relative efficacy of sirolimus-eluting stents (Cypher) as compared with that of bare stents with thin struts (BeStent 2). METHODS AND RESULTS: A total of 500 patients with coronary artery disease were randomly assigned to receive a Cypher stent or BeStent. The primary endpoint was angiographic restenosis defined as a stenosis diameter > or = 50% at 6-month angiographic follow-up. The secondary endpoint was the need for target vessel revascularization (TVR) during the year following the procedure. Follow-up angiography was performed in 81.8% of the patients. Patients treated with Cypher stents had a lower angiographic restenosis rate [8.3 vs. 25.5%, relative risk, 0.33 (95% confidence interval, 0.19-0.56), P<0.001] and a lower incidence of TVR [7.2 vs. 18.8%, relative risk, 0.38 (0.22-0.66), P<0.001]. For smaller vessels (< 2.8 mm), the angiographic restenosis rates were 7.0% with the Cypher stent and 34.2% with the BeStent (P<0.001). For larger vessels (> or = 2.8 mm), angiographic restenosis rates were 10.0% with the Cypher stent and 13.1% with the BeStent (P=0.52). CONCLUSION: The drug-eluting stent, Cypher, is associated with a significantly lower risk of restenosis compared with the bare thin-strut BeStent. The advantage of the Cypher stent is vastly reduced in large vessels.

PMID: 15737962 [PubMed - indexed for MEDLINE]Free Article

64.

Am Heart J. 2008 Feb;155(2):215-23.

Design of the Future REvascularization Evaluation in patients with Diabetes mellitus: Optimal management of Multivessel disease (FREEDOM) Trial.

Farkouh ME, Dangas G, Leon MB, Smith C, Nesto R, Buse JB, Cohen DJ, Mahoney E, Sleeper L, King S 3rd, Domanski M, McKinlay S, Fuster V.

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Abstract

BACKGROUND: Prior randomized trials suggested that revascularization of diabetic patients by coronary artery bypass grafting (CABG) produced results superior to balloon angioplasty. The introduction of drug-eluting stents (DESs) calls into question the relevance of past studies to the current era. The FREEDOM Trial is designed to determine whether CABG or percutaneous coronary intervention (PCI) is the superior approach for revascularization of diabetic patients. STUDY DESIGN: The FREEDOM Trial is a multicenter, open-label prospective randomized superiority trial of PCI versus CABG in at least 2000 diabetic patients in whom revascularization is indicated. Consenting diabetic patients with multivessel disease will be randomized on a 1:1 basis to either CABG or multivessel stenting using DESs and observed at 30 days, 1 year, and annually for up to 5 years. At the discretion of the primary physician or interventionalists, patients randomized to the PCI/DES arm will receive any approved DESs. The primary outcome measure is the composite of all-cause mortality, nonfatal myocardial infarction, or stroke. Patients will be observed for a mean of 4 years. IMPLICATIONS: At present, coronary revascularization with CABG surgery is the treatment of choice in diabetic patients with multivessel coronary artery disease. Drug-eluting stents have shown promising preliminary results in the diabetic population. The FREEDOM Trial is an international study designed to define the optimal revascularization strategy for the diabetic patient with multivessel coronary disease.

PMID: 18215589 [PubMed - indexed for MEDLINE]

Related citations

65.

Circ J. 2008 Jan;72(1):35-9.

Randomized comparison of cilostazol vs clopidogrel after drug-eluting stenting in diabetic patients--clilostazol for diabetic patients in drug-eluting stent (CIDES) trial.

Ahn Y, Jeong MH, Jeong JW, Kim KH, Ahn TH, Kang WC, Park CG, Kim JH, Chae IH, Nam CW, Hur SH, Bae JH, Kim KY, Oh SK.

Heart Center, Chonnam National University Hospital, Gwangju, South Korea.

Abstract

BACKGROUND: Previous studies have shown that cilostazol may not only prevent stent thrombosis, but may also have positive effect in the prevention of restenosis. However, the effect of cilostazol on restenosis after successful deployment of drug-eluting stent (DES) in patients with diabetes mellitus has not been evaluated. METHODS AND RESULTS: A total of 280 patients at 8 clinical sites were randomized. The patients (61.7+/-9.9 years old, 163 males) who underwent successful stenting were randomized to aspirin and cilostazol (group I, n=141, 61.2+/-9.6 years old) vs aspirin and clopidogrel (group II, n=139, 62.0+/-10.0 years old) after 1 month of aspirin, cilostazol, and clopidogrel combination treatment. There were no significant differences in baseline characteristics of the groups. The type of DES implanted did not differ between the groups. There were no differences in angiographic and procedural characteristics of the groups. Major adverse cardiac events, including acute and subacute stent thrombosis within 1 month, did not occur in either group. Cases of angiographic late stent thrombosis were 1 (0.9%) in group I and 1 (0.8%) in group II. Follow-up coronary angiography was performed in 237 patients (84.6%). Mean follow-up duration was 7.1 months. The rate of angiographic restenosis (stent plus 5-mm borders) was 9 (8.0%) in group I and 20 (16.1%) in group II, p=0.041). The minimal luminal diameter at follow-up period in group I was 2.55+/-0.63 mm compared with 2.41+/-0.83 mm in group II (p=NS). CONCLUSIONS: Combination therapy with aspirin and cilostazol for the prevention of stent restenosis is comparable or superior to that of aspirin and clopidogrel in diabetic patients who undergo DES implantation.

PMID: 18159096 [PubMed - indexed for MEDLINE]Free Article

Related citations

66.

Am Heart J. 2008 Jan;155(1):108-13. Epub 2007 Sep 14.

Comparison of vascular response to zotarolimus-eluting stent versus sirolimus-eluting stent: intravascular ultrasound results from ENDEAVOR III.

Miyazawa A, Ako J, Hongo Y, Hur SH, Tsujino I, Courtney BK, Hassan AH, Kandzari DE, Honda Y, Fitzgerald PJ; ENDEAVOR III Investigators.

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Abstract

BACKGROUND: The purpose of this study was to investigate the vascular response of zotarolimus-eluting stent (ZES) and sirolimus-eluting stent (SES) using serial intravascular ultrasound (IVUS). METHODS: Data were obtained from the Endeavor Drug-Eluting Coronary Stent System Versus the Center Siromlimus-Eluting Coronary Stent System in De Novo Native Coronary Artery Lesions (ENDEAVOR) III trial, a randomized study comparing ZES and SES for the treatment of de novo native coronary artery lesions. Serial (baseline and 8-month follow-up) IVUS was available in 258 patients (190 ZES, 68 SES). RESULTS: At 8 months, ZES had greater percentage of neointimal volume index (ZES 1.1 +/- 0.8 mm3/mm vs SES 0.2 +/- 0.1 mm3/mm, P < .01), resulting in smaller lumen volume index (6.0 +/- 2.0 mm3/mm vs 7.0 +/- 2.1 mm3/mm, P < .05). Zotarolimus-eluting stents showed larger IVUS-detectable neointimal coverage over stent surface (50.2% vs 10.5%, P < .01) and greater mean neointimal thickness (0.19 +/- 0.07 mm vs 0.10 +/- 0.06 mm, P < .01). Zotarolimus-eluting stents had a significantly lower incidence of late-acquired incomplete stent apposition. CONCLUSIONS: Zotarolimus-eluting stent is associated with a significantly greater amount of neointimal hyperplasia compared with SES. This amount of hyperplasia in ZES is distributed throughout the stent at 8-month follow-up.

PMID: 18082499 [PubMed - indexed for MEDLINE]

67.

Heart. 2008 May;94(5):604-9. Epub 2007 Dec 10.

Effects of stem cell therapy with G-CSF on coronary artery after drug-eluting stent implantation in patients with acute myocardial infarction.

Kang HJ, Kim YS, Koo BK, Park KW, Lee HY, Sohn DW, Oh BH, Park YB, Kim HS.

Innovative Research Institute for Cell Therapy/Cardiovascular Center, Seoul National University Hospital, Seoul, Korea.

Abstract

OBJECTIVE: The effects of stem cell therapy on the coronary vasculature were investigated in patients with acute myocardial infarction who underwent peripheral blood stem cell (PBSC) therapy in the MAGIC Cell-3-DES study. METHODS: Among 50 patients with acute myocardial infarction who underwent either sirolimus-eluting stent or paclitaxel-eluting stent implantation for the culprit lesion, intravascular ultrasound was analysed in 36 patients (cell infusion: n = 19 and control: n = 17). In the cell infusion group, PBSCs mobilised by granulocyte-colony stimulating factor were delivered via intracoronary infusion into infarcted myocardium. Proximal and distal reference segments, and stented segments, were evaluated with intravascular ultrasound at immediate post-intervention and 6-month follow-up, respectively. RESULTS: In the proximal and distal reference segments, the serial changes of lumen area, vessel area, and plaque plus media area were not significantly different between the cell infusion and the control groups. Within stented segments, mean neointimal area was similar in the two groups (cell infusion: 0.2 (SD 0.5) mm(2) vs control: 0.3 (SD 0.4) mm(2), p>0.05). However, there was a significant increase in mean peri-stent area of stented segment in the cell infusion group compared with the control group (0.7 (SD 1.4) mm(2) vs -0.1 (SD 1.2) mm(2), p<0.05). This difference mainly came from paclitaxel-eluting stent-implanted patients. CONCLUSION: Intracoronary infusion of PBSCs mobilised with G-CSF does not aggravate de novo atherosclerotic lesion and neointimal hyperplasia with DES implantation. However, it may induce peri-stent tissue growth at the stented segment, especially in patients receiving PES. Its clinical significance needs to be evaluated with long-term follow-up.

PMID: 18070947 [PubMed - indexed for MEDLINE]

Cardiovasc Revasc Med. 2007 Oct-Dec;8(4):230-5.

First human experience with local delivery of novel antisense AVI-4126 with Infiltrator catheter in de novo native and restenotic coronary arteries: 6-month clinical and angiographic follow-up from AVAIL study.

Kipshidze N, Iversen P, Overlie P, Dunlap T, Titus B, Lee D, Moses J, O'Hanley P, Lauer M, Leon MB.

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Abstract

BACKGROUND: A novel antisense phosphorodiamidate morpholino oligomer, AVI-4126, was shown to be effective in reducing neointimal formation in different animal models following delivery by pluronic gels, porous balloon catheters, and coated stents. The purpose of the AVAIL study was to investigate both the safety and the efficacy of AVI-4126 delivered locally via Infiltrator catheter after percutaneous coronary intervention in humans. METHODS: The AVAIL trial is a prospective, evaluator-blinded, randomized study including clinical follow-up at 30 days and 6 months after intervention and 6-month angiographic and intravascular ultrasound (IVUS) follow-up. An Infiltrator catheter was advanced to target lesion and either drug was delivered (Groups A and B) or catheter was advanced (Group C) after stent implantation in de novo lesions or percutaneous transluminal coronary angioplasty in restenotic lesions. Primary end points include major adverse cardiovascular events (MACE), target vessel revascularization (TVR), angiographic restenosis, and IVUS at 6 months. RESULTS: Forty-four patients with either de novo lesions or restenosis were randomized into three groups: (A) low dose, 3 mg (19 patients); (B) high dose, 10 mg (15 patients), and (C) control (10 patients). Baseline angiographic characteristics did not differ between the groups (reference vessel diameter, 2.5-4 mm; lesion length, <16 mm). Procedural success was 81. 82% (unable to advance Infiltrator catheter to target lesion in 8 patients, 5 from Group B and 3 from Group C). There was no in-hospital or 30-day MACE recorded in any group. Clinical follow-up was available in 25 patients. At 6 months, four patients (50%) from the control group (Group C, n=8) and 7 (100%) patients from the low-dose group (Group A, n=7) required TVR. In contrast, in the high-dose group (Group B, n=10) only 1 patient (10%) needed TVR. Angiographic follow-up in 25 patients (Group A, 8 patients; Group B, 7 patients; and Group C, 10 patients) demonstrated late loss of 1.4+ to 0.54, 0.8+ to 0.55, and 1.5+ to 0.65, respectively (P=.025). Binary restenosis was 38% in Group C (control), 29% in Group A (low dose), and 0% in Group B (high dose). CONCLUSION: Local delivery of antisense is feasible. These preliminary findings from the small

cohort of patients require confirmation in a larger trial utilizing more sophisticated drug-eluting technologies.

PMID: 18053943 [PubMed - indexed for MEDLINE]

69.

Am J Cardiol. 2007 Dec 1;100(11):1625-9. Epub 2007 Oct 10.

Comparison of effects of telmisartan and valsartan on late lumen loss and inflammatory markers after sirolimus-eluting stent implantation in hypertensive patients.

Hong SJ, Shim WJ, Choi JI, Joo HJ, Shin SY, Park SM, Lim SY, Lim DS.

Department of Cardiology, Cardiovascular Center, Korea University Anam Hospital, Seoul, Korea.

Abstract

We compared the effects of telmisartan and valsartan on late lumen loss and inflammatory markers after sirolimus-eluting stent implantation in hypertensive patients. This was a prospective, randomized, single-blinded, 8-month follow-up study that included hypertensive patients with significant coronary artery stenosis treated with telmisartan (n=79) or valsartan (n=80). Risk factors such as diabetes, hyperlipidemia, smoking, and obesity were similar between groups. After 8 months of follow-up, only the telmisartan group showed significant decreases in interleukin-6 and tumor necrosis factor-alpha. The decreases from baseline level in total cholesterol and low-density lipoprotein cholesterol concentrations were significantly greater in the telmisartan group. The increase in adiponectin concentrations from baseline measurements was significantly greater in the telmisartan group than in the valsartan group (1.9+/-2.7 vs 0.4+/-2.0 microg/ml, respectively, $p<0.05$). Moreover, late lumen loss was significantly lower in the telmisartan group than in the valsartan group (0.1+/-0.4 vs 0.3+/-0.5 mm, respectively, $p=0.001$). Major adverse cardiac events were similar between groups. In conclusion, compared with valsartan, telmisartan was associated with a significant decrease in late lumen loss and inflammatory markers after sirolimus-eluting stent implantation in hypertensive patients with significant coronary narrowing.

PMID: 18036359 [PubMed - indexed for MEDLINE]

70.

Int J Cardiol. 2008 Apr 25;125(3):397-403. Epub 2007 Nov 19.

Debulking of chronic coronary total occlusions with rotational or directional atherectomy before stenting: Final results of DOCTORS study.

Tsuchikane E, Suzuki T, Asakura Y, Oda H, Ueda K, Tanaka T, Matsubara T, Hsu YS, Tamai H, Katoh O; DOCTORS Investigators.

Collaborators (15)
Fujii K, Nishikawa H, Hamazaki Y, Oku K, Hayashi T, Yasaka Y, Kijima M, Aizawa T, Sumitsuji S, Hirokami M, Hosokawa H, Nozaki E, Tamaki K, Isshiki T, Kozuma K.

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Abstract

OBJECTIVE: To evaluate the safety and efficacy of pre-stent plaque debulking strategy for percutaneous coronary intervention for CTO. BACKGROUND: Drug-eluting stents (DES) reduce lesion recurrence after percutaneous coronary intervention for chronic total occlusion (CTO). However, massive plaque burden or calcified plaque sometime hinders optimal stenting. The aim of the study was to investigate the safety and the effectiveness of pre-stent plaque debulking in CTOs. The primary end-point was the angiographic restenosis rate at 6 months. Secondary end-points were the major adverse cardiac event (MACE) at 30 days and at 1 year. METHOD: Between October 2000 and July 2003, 266 patients with CTOs were evaluated in 21 Japanese centers. After successful wire crossing, an operator judged the indications for a debulking strategy (177 patients for rotational and 89 for directional atherectomy). The subjects were then randomly assigned to a debulking (rotational: 90, directional: 48) or non-debulking (rotational: 87, directional: 41) group. RESULT: Baseline clinical and lesion characteristics showed no differences between the groups. The debulking group tended to have the higher 30-day MACE rate than the non-debulking group (15.9% vs 8.5%, P=0.07). Although binary 6 month restenosis rates did not reach statistical significance (debulking 23.8% vs non-debulking 34.6%; P=0.072), the 1-year MACE rate was lower in the debulking group than in the non-debulking group (27.5% vs 39.8%; P=0.033). CONCLUSION: This study demonstrated that pre-stent plaque debulking of

CTO was associated with a favorable mid-term outcome with lower target revascularization rate in the debulking group than in the non-debulking group.

PMID: 18023899 [PubMed - indexed for MEDLINE]

71.

Am J Cardiol. 2007 Oct 22;100(8B):62M-70M.

The relation between clinical features, angiographic findings, and the target lesion revascularization rate in patients receiving the endeavor zotarolimus-eluting stent for treatment of native coronary artery disease: an analysis of ENDEAVOR I, ENDEAVOR II, ENDEAVOR II Continued Access Registry, and ENDEAVOR III.

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Abstract

The clinical and angiographic factors that predict clinically driven target lesion revascularization (TLR) in patients treated with the zotarolimus-eluting stent (ZES) are not known. Accordingly, the differences between ZES-treated patients who required TLR and ZES-treated patients who did not require TLR were examined in 1,306 patients enrolled in 4 pivotal trials of the Endeavor ZES (Medtronic Vascular, Santa Rosa, CA) for the treatment of symptomatic native coronary artery disease. TLR was performed in 64 patients (4.9%) by 9 months, with most cases (89.1%) occurring after 30 days. ZES-treated patients who required TLR had a greater incidence of 2- or 3-vessel disease ($p < 0.01$), more stents implanted ($p = 0.05$), and lower device ($p = 0.04$) and procedure ($p < 0.01$) success rates than ZES-treated patients who did not require TLR. The stents implanted in ZES-treated patients who later required TLR were also longer ($p = 0.02$) and smaller in diameter ($p < 0.01$). Most angiographic outcomes at 8 months (12 months for ZES-treated patients in ENDEAVOR I) were worse for ZES-treated patients who later required TLR. At 9 months, 10.9% of the ZES-treated patients who required TLR had had myocardial infarctions, compared with 2.2% who did not require TLR ($p = 0.001$). Multivariate analysis identified older age (odds ratio [OR], 1.03; 95% confidence interval [CI], 1.00-1.06), male sex (OR, 1.79; 95% CI, 0.88-3.65), and longer lesion length (OR, 1.03; 95% CI, 0.99-1.07) as risk factors for TLR after ZES implantation (with a C statistic of 0.61, suggesting a modest discriminatory

value). These data provide insight into the clinical and angiographic factors that predict TLR at 9 months in ZES-treated patients, making possible the focused surveillance of selected ZES-treated patients who might be at greater risk of TLR.

PMID: 17950834 [PubMed - indexed for MEDLINE]

Related citations

72.

Ann Intern Med. 2007 Nov 20;147(10):703-16. Epub 2007 Oct 15.

Systematic review: the comparative effectiveness of percutaneous coronary interventions and coronary artery bypass graft surgery.

Bravata DM, Gienger AL, McDonald KM, Sundaram V, Perez MV, Varghese R, Kapoor JR, Ardehali R, Owens DK, Hlatky MA.

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Comment in:

- Ann Intern Med. 2007 Nov 20;147(10):732-4.
- ACP J Club. 2008 Mar-Apr;148(2):44.

Abstract

BACKGROUND: The comparative effectiveness of coronary artery bypass graft (CABG) surgery and percutaneous coronary intervention (PCI) for patients in whom both procedures are feasible remains poorly understood. PURPOSE: To compare the effectiveness of PCI and CABG in patients for whom coronary revascularization is clinically indicated. DATA SOURCES: MEDLINE, EMBASE, and Cochrane databases (1966-2006); conference proceedings; and bibliographies of retrieved articles. STUDY SELECTION: Randomized, controlled trials (RCTs) reported in any language that compared clinical outcomes of PCI with those of CABG, and selected observational studies. DATA EXTRACTION: Information was extracted on study design, sample characteristics, interventions, and clinical outcomes.

DATA SYNTHESIS: The authors identified 23 RCTs in which 5019 patients were randomly assigned to PCI and 4944 patients were randomly assigned to CABG. The difference in survival after PCI or CABG was less than 1% over 10 years of follow-up. Survival did not differ between PCI and CABG for patients with diabetes in the 6 trials that reported on this subgroup. Procedure-related strokes were more common after CABG than after PCI (1.2% vs. 0.6%; risk difference, 0.6%; P = 0.002). Angina relief was greater after CABG than after PCI, with risk differences ranging from 5% to 8% at 1 to 5 years (P < 0.001). The absolute rates of angina relief at 5 years were 79% after PCI and 84% after CABG. Repeated revascularization was more common after PCI than after CABG (risk difference, 24% at 1 year and 33% at 5 years; P < 0.001); the absolute rates at 5 years were 46.1% after balloon angioplasty, 40.1% after PCI with stents, and 9.8% after CABG. In the observational studies, the CABG-PCI hazard ratio for death favored PCI among patients with the least severe disease and CABG among those with the most severe disease. LIMITATIONS: The RCTs were conducted in leading centers in selected patients. The authors could not assess whether comparative outcomes vary according to clinical factors, such as extent of coronary disease, ejection fraction, or previous procedures. Only 1 small trial used drug-eluting stents. CONCLUSION: Compared with PCI, CABG was more effective in relieving angina and led to fewer repeated revascularizations but had a higher risk for procedural stroke. Survival to 10 years was similar for both procedures.

PMID: 17938385 [PubMed - indexed for MEDLINE]Free Article

73.

Am Heart J. 2007 Oct;154(4):669-75.

Comparison of angiographically guided direct stenting technique with direct stenting and optimal balloon angioplasty guided with intravascular ultrasound. The multicenter, randomized trial results.

Gil RJ, Pawłowski T, Dudek D, Horszczaruk G, Zmudka K, Lesiak M, Witkowski A, Ochała A, Kubica J; Investigators of Direct Stenting vs Optimal Angioplasty Trial (DIPOL).

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Abstract

AIM: The primary objective of the trial was to test the hypothesis that intravascular ultrasound (IVUS) guidance for coronary angioplasty is superior to the quantitative coronary angiography approach both during stenting and plain balloon angioplasty. METHODS: Two hundred fifty-nine patients (70 females, 189 males; mean age, 54 +/- 9) were enrolled into our study. They were randomized into 3 groups: group 1--direct stenting guided with quantitative coronary angiography; group 2--direct stenting guided with IVUS; group 3--optimal balloon angioplasty guided with IVUS. At 6-month follow-up, we recorded evidence of major adverse cardiac events (death, myocardial infarction, repeat coronary revascularization). RESULTS: Procedural success was achieved in 95% of cases. At 6-month follow-up, the evidence of composite end point (major adverse cardiac events) was 16.2%, 7.3%, and 21.8% in groups 1, 2, and 3, respectively ($P < .05$). Use of IVUS led to 55% reduction of the primary end point between group 1 and group 2. The same when compared to the balloon angioplasty group assumed 66% reduction. CONCLUSION: Ultrasound guidance for direct stenting is the most effective for long-term outcome in comparison with other strategies. It is very likely that bigger lumen gain due to appropriate device sizing is responsible for better outcome. Direct stenting guided with IVUS might be an alternative option for patients requiring coronary revascularization and have contraindications to prolonged antiplatlet therapy as is mandatory for drug-eluting stent implantation.

PMID: 17892989 [PubMed - indexed for MEDLINE]

Related citations

74.

Am Heart J. 2007 Oct;154(4):632-6.

Rationale and design of the Fractional Flow Reserve versus Angiography for Multivessel Evaluation (FAME) study.

Fearon WF, Tonino PA, De Bruyne B, Siebert U, Pijls NH; FAME Study Investigators.

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Erratum in:

- Am Heart J. 2007 Dec;154(6):1243.

Abstract

BACKGROUND: Although its limitations for diagnosing critical coronary artery disease are well described, coronary angiography remains the predominant method for guiding decisions about stent implantation in patients with multivessel coronary artery disease. However, some have suggested that invasive physiologic guidance may improve decision making. TRIAL DESIGN: The objective of this multicenter, randomized clinical trial is to compare the efficacy of 2 strategies, one based on angiographic guidance to one based on physiologic guidance with fractional flow reserve (FFR), for deciding which coronary lesions to stent in patients with multivessel coronary disease. Eligible patients must have coronary narrowings > 50% diameter stenosis in > or = 2 major epicardial vessels, > or = 2 of which the investigator feels require drug-eluting stent placement. Patients with previous coronary bypass surgery or left main coronary disease are excluded. Based on angiographic evaluation, the investigator notes the lesions that require stenting. The patient is then randomly assigned to either angiographic guidance or FFR guidance. Patients assigned to angiographic guidance undergo stenting as planned. Patients assigned to FFR guidance first have FFR measured in each diseased vessel and only undergo stenting if the FFR is < or = 0.80. The primary end point of the study is a composite of major adverse cardiac events, including death, myocardial infarction, and repeat coronary revascularization, at 1 year. Secondary end points will include the individual adverse events, cost-effectiveness, quality of life, and 30-day, 6-month, 2-year, and 5-year outcomes. CONCLUSION: The FAME study will examine for the first time in a large, multicenter, randomized fashion the role of measuring FFR in patients undergoing multivessel percutaneous coronary intervention.

PMID: 17892983 [PubMed - indexed for MEDLINE]

75.

Am J Cardiol. 2007 Oct 1;100(7):1103-8. Epub 2007 Jul 18.

Comparison of triple versus dual antiplatelet therapy after drug-eluting stent implantation (from the DECLARE-Long trial).

Lee SW, Park SW, Kim YH, Yun SC, Park DW, Lee CW, Hong MK, Kim HS, Ko JK, Park JH, Lee JH, Choi SW, Seong IW, Cho YH, Lee NH, Kim JH, Chun KJ, Park SJ; DECLARE-Long Study Investigators.

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Abstract

To evaluate the impact of cilostazol on neointimal hyperplasia after drug-eluting stent (DES) implantation for long coronary lesions, we performed a randomized multicenter prospective study comparing triple antiplatelet therapy (aspirin, clopidogrel, and cilostazol; triple group, n = 250) and dual antiplatelet therapy (aspirin and clopidogrel; standard group, n = 250) for 6 months in patients with long lesions (> or =25 mm) requiring a long DES (> or =32 mm). The primary end point was in-stent late loss at 6-month angiography. The 2 groups had similar baseline clinical and angiographic characteristics. In-stent late loss (0.22 +/- 0.48 mm vs 0.32 +/- 0.51 mm, p = 0.031) and in-segment late loss (0.34 +/- 0.49 mm vs 0.51 +/- 0.49 mm, p = 0.001) at 6-month follow-up angiography were significantly lower in the triple group versus the standard group. There was a trend toward lower rates of in-segment restenosis in the triple group versus the standard group (6.7% vs 11.2%, p = 0.104). Target lesion revascularization (TLR; 2.8% vs 6.8%, p = 0.036) and major adverse cardiac events (2.8% vs 7.6%, p = 0.016), including death, myocardial infarction, and TLR at 9 months were significantly lower in the triple group than in the standard group. At 9 months, the 2 groups had similar rates of stent thrombosis (0.4% vs 0.4%, p = 0.999), death (0% vs 0.8%, p = 0.499), and myocardial infarction (0.4% vs 0.4%, p = 0.999). In conclusion, cilostazol significantly reduced late loss at 6 months after DES implantation and the occurrence of TLR and major adverse cardiac events in patients with long coronary lesions.

PMID: 17884371 [PubMed - indexed for MEDLINE]

Related citations

76.

J Am Coll Cardiol. 2007 Sep 18;50(12):1123-31. Epub 2007 Sep 4.

Impact of vessel size on outcome after implantation of sirolimus-eluting and paclitaxel-eluting stents: a subgroup analysis of the SIRTAX trial.

Togni M, Eber S, Widmer J, Billinger M, Wenaweser P, Cook S, Vogel R, Seiler C, Eberli FR, Maier W, Corti R, Roffi M, Lüscher TF, Garachemani A, Hess OM, Wandel S, Meier B, Jüni P, Windecker S.

Department of Cardiology, University Hospital Bern, Switzerland.

Comment in:

- Nat Clin Pract Cardiovasc Med. 2008 Apr;5(4):188-9.

Abstract

OBJECTIVES: We assessed the impact of vessel size on angiographic and long-term clinical outcome after percutaneous coronary intervention (PCI) with sirolimus-eluting stents (SES) and paclitaxel-eluting stents (PES) within a randomized trial (SIRTAX [Sirolimus-Eluting Stent Compared With Paclitaxel-Eluting Stent for Coronary Revascularization]). BACKGROUND: Percutaneous coronary intervention in small-vessel disease is associated with an increased risk of major adverse cardiac events (MACE). METHODS: A total of 1,012 patients were randomly assigned to treatment with SES (n = 503) or PES (n = 509). A stratified analysis of angiographic and clinical outcome was performed up to 2 years after PCI according to size of the treated vessel (reference vessel diameter < or =2.75 vs. >2.75 mm). RESULTS: Of 1,012 patients, 370 patients (37%) with 495 lesions underwent stent implantation in small vessels only, 504 patients (50%) with 613 lesions in large vessels only, and 138 patients (14%) with 301 lesions in both small and large vessels (mixed). In patients with small-vessel stents, SES reduced MACE by 55% (10.4% vs. 21.4%; p = 0.004), mainly driven by a 69% reduction of target lesion revascularization (TLR) (6.0% vs. 17.7%; p = 0.001) compared with PES at 2 years. In patients with large- and mixed-vessel stents, rates of MACE (large: 10.4% vs. 13.1%; p = 0.33; mixed: 16.7% vs. 18.0%; p = 0.83) and TLR (large: 6.9% vs. 8.6%; p = 0.47; mixed: 16.7% vs. 15.4%; p = 0.86) were similar for SES and PES. There were no significant differences with respect to death and myocardial infarction between the 3 groups. CONCLUSIONS: Compared with PES, SES more effectively reduced MACE and TLR in small-vessel disease. Differences between SES and PES appear less pronounced in patients with large- and mixed-vessel disease. (The SIRTAX trial; http://clinicaltrials.gov/ct/show/NCT00297661?order=1; NCT00297661).

PMID: 17868802 [PubMed - indexed for MEDLINE]

77.

Lancet. 2007 Aug 18;370(9587):567-74.

Effect of celecoxib on restenosis after coronary angioplasty with a Taxus stent (COREA-TAXUS trial): an open-label randomised controlled study.

Koo BK, Kim YS, Park KW, Yang HM, Kwon DA, Chung JW, Hahn JY, Lee HY, Park JS, Kang HJ, Cho YS, Youn TJ, Chung WY, Chae IH, Choi DJ, Oh BH, Park YB, Kim HS.

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Erratum in:

- Lancet. 2007 Sep 14;370(9590):828.

Comment in:

- Lancet. 2007 Aug 18;370(9587):541-2.

Abstract

BACKGROUND: In-vitro and animal experiments have shown that the cyclo-oxygenase 2 inhibitor celecoxib can reduce formation of neointima within stents. We aimed to test whether celecoxib has similar effects in a clinical setting. METHODS: In a randomised two-centre trial, we enrolled 274 patients who had angina pectoris or a positive stress test and who had native coronary artery lesions for which implantation of paclitaxel-eluting stents was feasible. All patients were given aspirin (100 mg daily) and clopidogrel (75 mg daily). 136 patients were randomly assigned to receive celecoxib (400 mg before the intervention, and 200 mg twice daily for 6 months after the procedure). The primary endpoint was late luminal loss on quantitative coronary angiography at 6 months after the intervention. Secondary endpoints were cardiac death, non-fatal myocardial infarction, and revascularisation of the target lesion. Analysis was done on a modified intention-to-treat basis. This study is registered with ClinicalTrials.gov, number NCT00292721. FINDINGS: At 6 months, mean in-stent late luminal loss was lower in the celecoxib group (0.49 mm, SD 0.47) than in the control group (0.75 mm, 0.60) (absolute difference 0.26 mm; 95% CI 0.12-0.40). Frequency of secondary outcomes at 6 months was also lower in the celecoxib group, mainly because of a reduced need for revascularisation of the target lesion. INTERPRETATION:

These data suggest that the adjunctive use of celecoxib for 6 months after stent implantation in patients with coronary artery disease is safe and can reduce the need for revascularisation of the target lesion.

PMID: 17707751 [PubMed - indexed for MEDLINE]

78.

Int J Cardiol. 2008 Aug 29;128(3):374-7. Epub 2007 Aug 8.

Functional result following direct coronary artery stenting with drug eluting stents in chronic stable angina is similar to stenting after balloon predilatation.

Balachandran KP, Singh B, Sandilands A, Popusoi G, Rubino P, Baumbach A.

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Abstract

BACKGROUND: The safety and efficacy of direct coronary artery stenting without predilatation using drug eluting stents has not been firmly established. Concerns have been raised that this technique may be associated with increased risk of immediate and short term complications. METHODS: 68 consecutive patients with chronic stable angina and angiographically proven single vessel disease were randomised to undergo either direct coronary artery stenting or stenting after balloon predilation. All patients underwent Pressure Wire directed percutaneous coronary intervention (PCI) and drug eluting stents were deployed. Pre and post-PCI fractional flow reserve (FFR) was assessed following administration of intravenous adenosine. Post-procedure troponin I (TNI) and creatine kinase-MB (CK-MB) were compared. 51 of the 68 patients successfully completed a 6 month treadmill exercise test. RESULTS: There were no significant differences in the demographic, risk factor or angiographic profiles between the two groups except for hyperlipedemia and statin therapy. Drug eluting stents were deployed in all patients. Majority of the lesions were relatively simple (all lesions were either type A or B1). The pre-procedure FFR [mean(SD)]was marginally lower in the pre-dilatation group compared to the direct stenting group [0.57(0.17) versus 0.64(018); p=0.04]. The post-procedure FFR was similar in both groups [0.97(0.05) versus 0.98(0.03); p=0.26]. There was no difference in the post-procedure rise of either TNI or CK-MB in both groups. At 6 months, no major adverse cardiac events (death, MI or

revascularisation) were observed in all patients. A positive exercise test was seen in 5 patients (10%) and there was no difference between the two groups. CONCLUSION: A strategy of direct stenting of appropriate coronary lesions with drug eluting stents in patients with chronic stable angina is associated with similar functional results as balloon predilatation followed by stenting.

PMID: 17689737 [PubMed - indexed for MEDLINE]

79.

Catheter Cardiovasc Interv. 2007 Dec 1;70(7):920-7.

Prospective randomized study of the restenotic process in small coronary arteries using a Carbofilm coated stent in comparison with plain old balloon angioplasty: a multicenter study.

Braun P; SMARTCOAST Study.

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Abstract

BACKGROUND: The optimal interventional approach to treat lesions in small coronary arteries is still undetermined and controversial. This randomized, multicenter trial was designed to compare the 6-months restenosis and clinical event rates in two treatment groups: balloon angioplasty as a primary strategy and provisional stenting versus primary implantation of a carbon coated stent (Carbosten). RESULTS: At 6 months the angiographic restenosis rate was significantly lower for the stented patients (11.6%) as compared to the balloon angioplasty patients (32.2%). However this advantage in restenosis rate did not translate into a clinical benefit in respect to target vessel revascularization rates. CONCLUSION: This trial demonstrated a remarkably low 6-months restenosis rate for lesions in small (<2.8 mm) coronary arteries treated with Carbosten implantation that is comparable to the rates found after drug eluting stent implantation and was significantly better in comparison to balloon angioplasty alone.

PMID: 17671956 [PubMed - indexed for MEDLINE]

80.

Catheter Cardiovasc Interv. 2007 Dec 1;70(7):946-51.

Efficacy of reduced-dose sirolimus-eluting stents in the human coronary artery: serial IVUS analysis of neointimal hyperplasia and luminal dimension.

Nakamura M, Abizaid A, Hirohata A, Honda Y, Sousa JE, Fitzgerald PJ.

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Abstract

STUDY OBJECTIVE: Using serial intravascular ultrasound (IVUS), the efficacy of reduced-dose sirolimus-eluting stents (SESs) in the prevention of neointimal hyperplasia (NH) and maintenance of luminal patency in human coronary arteries was evaluated. BACKGROUND: In the animal model, a broad therapeutic window regarding sirolimus doses in suppressing NH has been reported. METHODS: Serial cross-sectional and volumetric IVUS analyses were performed in 44 patients treated with SES that contained lower sirolimus doses (either 45% or 70%) than standard SES. For cross-sectional analysis, minimum lumen area (MLA) was measured. Percent (%) NH volumetric obstruction was calculated as 100 x NH volume/stent volume. RESULTS: IVUS measurements were similar between the two drug-dose groups. At 12 months follow-up, only one case developed late incomplete stent apposition. Between 4 and 12 months, a slight increase of in-stent % area loss and % NH obstruction was noted (3.5% +/- 10.4% to 6.7% +/- 10.7% and 1.9% +/- 5.0% to 4.4% +/- 8.0%, respectively). The majority of studied cases, however, sustained less than a 10% volumetric (93% of studied cases) and area loss (75% of studied cases) in the stented segment up to 12 months. At 12 months, % area loss within the stented segments and 5-mm reference segments were comparable (7.0% +/- 19.6% versus 6.7% +/- 10.7%). CONCLUSIONS: Although slight increases of NH were noted, SESs, delivering two reduced drug doses, appeared to be effective for maintaining luminal patency during 12 months follow-up.

PMID: 17621671 [PubMed - indexed for MEDLINE]

Related citations

J Am Coll Cardiol. 2007 Mar 27;49(12):1265-71.

Does addition of estradiol improve the efficacy of a rapamycin-eluting stent? Results of the ISAR-PEACE randomized trial.

Adriaenssens T, Mehilli J, Wessely R, Ndrepepa G, Seyfarth M, Wieczorek A, Blaich B, Iijima R, Pache J, Kastrati A, Schömig A.

Deutsches Herzzentrum, Technische Universtität, Munich, Germany.

Erratum in:

- J Am Coll Cardiol. 2007 May 8;49(18):1902.

Abstract

OBJECTIVES: This study aimed to assess the efficacy of a rapamycin plus 17-beta-estradiol-eluting stent versus a rapamycin-eluting stent in patients with coronary artery disease. BACKGROUND: Estradiol promotes rapid re-endothelialization of coronary stents in animal models, but it is not known whether combining this drug with rapamycin represents an improved drug-eluting stent technology in terms of reduced lumen renarrowing. METHODS: In this randomized study, we enrolled 502 patients with de novo lesions in native coronary arteries who were randomly assigned to receive either a polymer-free, estradiol plus rapamycin-eluting stent (ERES) (n = 252) or a polymer-free, rapamycin-eluting stent (RES) (n = 250). The primary end point was in-stent late lumen loss in the follow-up angiography. Secondary end points were binary angiographic restenosis, target lesion revascularization, combined incidence of death and myocardial infarction, and incidence of stent thrombosis during 1 year after randomization. The study was designed to test for the superiority of the ERES compared with the RES with respect to in-stent late lumen loss. RESULTS: Late lumen loss (0.52 +/- 0.58 mm vs. 0.51 +/- 0.58 mm, p = 0.83), the incidence of binary angiographic restenosis (17.6% vs. 16.9%, p = 0.85), the incidence of target lesion revascularization (14.3% vs. 13.2%, p = 0.72), the combined incidence of death and myocardial infarction (7.9% vs. 8.0%, p = 0.98), and the incidence of stent thrombosis (0.8% vs. 1.2%, p = 0.99) were not significantly different between the ERES group and the RES group. CONCLUSIONS: No apparent beneficial effect is obtained by adding estradiol to a polymer-free rapamycin-eluting stent during the first year after the procedure. (The ISAR-PEACE trial; http://clinicaltrials.gov/ct/show/NCT00402636?order=1; NCT00402636).

PMID: 17394956 [PubMed - indexed for MEDLINE]

82.

Eur Heart J. 2007 Feb;28(4):433-42. Epub 2007 Jan 31.

The clinical outcome of percutaneous treatment of bifurcation lesions in multivessel coronary artery disease with the sirolimus-eluting stent: insights from the Arterial Revascularization Therapies Study part II (ARTS II).

Tsuchida K, Colombo A, Lefèvre T, Oldroyd KG, Guetta V, Guagliumi G, von Scheidt W, Ruzyllo W, Hamm CW, Bressers M, Stoll HP, Wittebols K, Donohoe DJ, Serruys PW.

Thoraxcenter, Ba 583, Erasmus Medical Center, Dr. Molewaterplein 40, 3015 GD Rotterdam, The Netherlands.

Comment in:

- Eur Heart J. 2007 Feb;28(4):383-5.

Abstract

AIMS: Little is known about the impact of treating bifurcations on the overall outcome of multivessel coronary artery disease treated with stenting. This analysis was made to investigate the 1 year clinical outcome of the treatment of bifurcation lesions using sirolimus-eluting stents (SES) in patients with multivessel disease. METHODS AND RESULTS: Among a total of 607 patients (2160 lesions) in the Arterial Revascularization Therapies Study part II (ARTS II), there were 324 patients in whom at least one bifurcation lesion was treated (465 lesions). Patients with bifurcations were compared with those without bifurcations in terms of baseline characteristics and major adverse cardiac and cerebrovascular events (MACCE). Patients with 'true' (200 patients) vs. 'partial' bifurcations (124 patients) and usage of a one- (263 patients) vs. two-stent strategy (61 patients) were also evaluated. The bifurcation group was associated with more complex lesion and procedural characteristics than the non-bifurcation group. However, there was no significant difference in 1 year MACCE rates between the bifurcation group and the non-bifurcation group (13.3 vs. 11.0%, P=0.46). MACCE in patients with true bifurcations was 13.0 vs. 13.7% for partial bifurcations (P=0.87) and 14.1 vs. 9.8% for one- vs. two-stent strategy (P=0.53). CONCLUSIONS: In this trial without angiographic follow-up, the presence of bifurcations did not affect 1

year outcomes after SES implantation. The outcomes in true vs. partial bifurcations and using one vs. two stents were similar when the treatment strategies were left to the operator's discretion.

PMID: 17267457 [PubMed - indexed for MEDLINE]Free Article

83.

J Invasive Cardiol. 2006 Oct;18(10):475-9.

Direct versus predilatation drug-eluting stenting: a randomized clinical trial.

Katritsis DG, Korovesis S, Karvouni E, Giazitzoglou E, Theodorou S, Kourlaba G, Panagiotakos D, Voridis E.

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Abstract

BACKGROUND: Direct stenting without balloon predilatation has been shown to be feasible and safe with drug-eluting stents, but no randomized comparisons between the two strategies exist. This study was designed to compare direct stenting with balloon predilatation followed by stent placement using only drug-eluting stents. METHODS: One hundred and sixty-six consecutive coronary lesions in 95 consenting patients (mean age 59 +/- 11 years; 12 women) were randomly assigned to direct stenting (n = 88), or balloon predilatation followed by stenting (n = 78), using sirolimus- or paclitaxel-eluting stents. RESULTS: All procedures were uneventful. Crossover to balloon predilatation was necessary in 6 (7%) lesions randomized to direct stenting. During a 12-month follow up period, ischemia-driven angiography was performed in 13 patients. By intention to treat analysis, target lesion revascularization was required in 4 lesions, all of which were randomized to the predilatation group (p = 0.04). CONCLUSIONS: Direct stenting was feasible in up to 93% of attempted lesions. A strategy of direct stenting resulted in a significantly lower rate of target lesion revascularization over a 12-month follow-up period compared to balloon predilatation followed by stenting.

PMID: 17235419 [PubMed - indexed for MEDLINE]

84.

Eur Heart J. 2007 Jan;28(1):19-25. Epub 2006 Nov 28.

Pretreatment with intracoronary adenosine reduces the incidence of myonecrosis after non-urgent percutaneous coronary intervention: a prospective randomized study.

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Abstract

AIMS: We sought to investigate the effect of adenosine pretreatment on the incidence of myonecrosis after non-urgent percutaneous coronary intervention (PCI). METHODS AND RESULTS: This was a prospective, randomized, open-label study. Patients who were scheduled for non-urgent PCI in de novo native coronary arteries were eligible. All patients were pretreated with aspirin and clopidogrel. Myonecrosis was measured by creatine kinase-myocardial band (CK-MB) elevation after PCI. A total of 62 patients were randomized into the adenosine (n = 31) or standard (n = 31) group. The adenosine group received 50 microg adenosine bolus before wiring of each lesion, whereas the standard group did not. Post-PCI myonecrosis occurred more frequently in the standard group (39 vs. 13%, OR 0.23, 95% CI 0.05-0.95, P = 0.020). After adjustment for drug-eluting stent implantation, multi-vessel stenting, and elevated baseline troponin, the OR was 0.19 (95% CI 0.05-0.72, P = 0.017). The median peak values of CK-MB in the adenosine and standard groups were 2 and 4 microg/L, respectively (P = 0.033). The adjusted difference was 1.95 microg/L (95% CI 0.13-3.77, P = 0.037). The incidences of myocardial infarction (>3 x CK-MB) were 6 and 16% in the adenosine and standard groups, respectively (OR 0.36; 95% CI 0.03-2.46, P = 0.229). CONCLUSION: Pretreatment with 50 microg of adenosine decreases the incidence of myonecrosis after non-urgent PCI compared with that without pretreatment.

PMID: 17132650 [PubMed - indexed for MEDLINE]Free Article

85.

N Engl J Med. 2006 Nov 16;355(20):2113-24. Epub 2006 Nov 13.

Treatment of coronary in-stent restenosis with a paclitaxel-coated balloon catheter.

Scheller B, Hehrlein C, Bocksch W, Rutsch W, Haghi D, Dietz U, Böhm M, Speck U.

Universitätsklinikum des Saarlandes, Homburg/Saar, Germany. bruno.scheller@uniklinikum-saarland.de

Comment in:

- N Engl J Med. 2007 Mar 8;356(10):1071; author reply 1072-3.
- N Engl J Med. 2006 Nov 16;355(20):2149-51.
- N Engl J Med. 2007 Mar 8;356(10):1071-2; author reply 1072-3.

Abstract

BACKGROUND: Treatment of coronary in-stent restenosis is hampered by a high incidence of recurrent in-stent restenosis. We assessed the efficacy and safety of a paclitaxel-coated balloon in this setting. METHODS: We enrolled 52 patients with in-stent restenosis in a randomized, double-blind, multicenter trial to compare the effects of a balloon catheter coated with paclitaxel (3 microg per square millimeter of balloon surface area) with those of an uncoated balloon catheter in coronary angioplasty. The primary end point was late luminal loss as seen on angiography. Secondary end points included the rates of restenosis (a binary variable) and major adverse cardiac events. RESULTS: Multivessel disease was present in 80% of patients in both groups. Quantitative coronary angiography revealed no significant differences in baseline measures. At 6 months, angiography showed that the mean (+/-SD) in-segment late luminal loss was 0.74+/-0.86 mm in the uncoated-balloon group versus 0.03+/-0.48 mm in the coated-balloon group (P=0.002). A total of 10 of 23 patients (43%) in the uncoated-balloon group had restenosis, as compared with 1 of 22 patients (5%) in the coated-balloon group (P=0.002). At 12 months, the rate of major adverse cardiac events was 31% in the uncoated-balloon group and 4% in the coated-balloon group (P=0.01). This difference was primarily due to the need for target-lesion revascularization in six patients in the uncoated-balloon group (P=0.02). CONCLUSIONS: Treatment of coronary in-stent restenosis with paclitaxel-coated balloon catheters significantly reduced the incidence of restenosis. These data suggest that the inhibition of restenosis by local drug delivery may not require stent implantation and sustained drug release at the site of injury. (ClinicalTrials.gov number, NCT00106587 [ClinicalTrials.gov].).

PMID: 17101615 [PubMed - indexed for MEDLINE]Free Article

86.

Am Heart J. 2006 Nov;152(5):915-20.

Comparison between stenting and balloon angioplasty in patients undergoing primary angioplasty of small coronary vessels.

De Luca G, Suryapranata H, van 't Hof AW, Ottervanger JP, Hoorntje JC, Dambrink JH, Gosselink AT, de Boer MJ.

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Abstract

BACKGROUND: Primary angioplasty has been shown to improve outcomes in selected patients with ST-segment elevation myocardial infarction. However, no information has been reported so far in small vessels. In the Zwolle-6 randomized trial, consecutive patients with ST-segment elevation myocardial infarction were randomized to stenting or to balloon angioplasty without any exclusion criterion. In this study, we present data on patients with small vessels (< 3.0 mm). METHODS: From April 1997 to October 2001, 798 patients randomized to balloon angioplasty or to stenting before their initial angiogram underwent primary angioplasty of small vessels, defined according to a postprocedural reference diameter < or = 3 mm. One-year follow-up data were available from all patients. RESULTS: Three hundred eighty-seven patients were randomized to stent, whereas 411 were to balloon. The crossover rates from balloon to stent and from stent to balloon were 28% and 13.9%, respectively (P < .001). The groups were comparable in terms of postprocedural TIMI flow, myocardial blush grade, distal embolization, and ST-segment resolution. No difference was observed in 1-year mortality (7.2% vs 5.8%, P = not significant [NS]), target vessel revascularization (17.8% vs 22.1%, P = NS), and major adverse cardiac events (24.8% vs 29.0%, P = NS) between the groups. CONCLUSIONS: As compared with balloon angioplasty, routine stenting does not seem to improve clinical outcomes in patients undergoing primary angioplasty of small vessels. Future trials are certainly needed to evaluate the safety and benefits of drug-eluting stents in this high-risk subset of patients.

PMID: 17070158 [PubMed - indexed for MEDLINE]

Related citations

87.

Am Heart J. 2006 Nov;152(5):887.e1-7.

The favorable clinical and angiographic outcomes of a high-dose dexamethasone-eluting stent: randomized controlled prospective study.

Han SH, Ahn TH, Kang WC, Oh KJ, Chung WJ, Shin MS, Koh KK, Choi IS, Shin EK.

Cardiology, Gachon Medical School, Incheon, South Korea.

Abstract

BACKGROUND: Previous studies with dexamethasone-eluting stents could not elucidate the role of dexamethasone in the prevention of neointimal hyperplasia because they did not compare their results with a control group. We prospectively evaluated the clinical and angiographic outcomes of dexamethasone-eluting stents, comparing them with unloaded stents of an identical design. METHODS: A total of 92 patients (98 lesions) were randomly assigned to the dexamethasone group (67 patients, 71 lesions) or control group (25 patients, 27 lesions). The inclusion criteria for a stent implantation were a de novo lesion with a diameter of 2.60 to 4.0 mm. BiodivYsio Drug Delivery phosphorylcholine-coated stents (Biocompatibles Ltd, Galway, Ireland) were immersed in a 20-mg/mL dexamethasone solution, yielding a total dexamethasone dose of 0.5 microg/mm2 per stent. RESULTS: The total major adverse cardiac events rate at 12 months was significantly lower in the dexamethasone group, as compared with the control group (10.4% [7/67] vs 28.0% [7/25], P = .037). The binary restenosis rate at 6 months was 11.9% (7/59) in the dexamethasone group and 42.9% (9/21) in the control group (P = .002). The use of dexamethasone-eluting stents was the only independent predictor for the major adverse cardiac event at 12 months (relative risk 0.20, 95% CI 0.06-0.68, P = .009) and binary restenosis at 6 months (relative risk 0.17, 95% CI 0.05-0.60, P = .006) by multivariate analysis. CONCLUSIONS: Dexamethasone-eluting stents exhibited an improvement in the clinical and angiographic outcomes, as compared with the control stents. These results suggest that dexamethasone may play an important role in the inhibition of the polymer-induced inflammation in the era of drug-eluting stents.

PMID: 17070150 [PubMed - indexed for MEDLINE]

88.

Circulation. 2006 Oct 31;114(18):1955-61. Epub 2006 Oct 23.

Randomized study on simple versus complex stenting of coronary artery bifurcation lesions: the Nordic bifurcation study.

Steigen TK, Maeng M, Wiseth R, Erglis A, Kumsars I, Narbute I, Gunnes P, Mannsverk J, Meyerdierks O, Rotevatn S, Niemelä M, Kervinen K, Jensen JS, Galløe A, Nikus K, Vikman S, Ravkilde J, James S, Aarøe J, Ylitalo A, Helqvist S, Sjögren I, Thayssen P, Virtanen K, Puhakka M, Airaksinen J, Lassen JF, Thuesen L; Nordic PCI Study Group.

Department of Cardiology, University Hospital of Tromsoe, Tromsoe, Norway.

Abstract

BACKGROUND: The optimal stenting strategy in coronary artery bifurcation lesions is unknown. In the present study, a strategy of stenting both the main vessel and the side branch (MV+SB) was compared with a strategy of stenting the main vessel only, with optional stenting of the side branch (MV), with sirolimus-eluting stents. METHODS AND RESULTS: A total of 413 patients with a bifurcation lesion were randomized. The primary end point was a major adverse cardiac event: cardiac death, myocardial infarction, target-vessel revascularization, or stent thrombosis after 6 months. At 6 months, there were no significant differences in rates of major adverse cardiac events between the groups (MV+SB 3.4%, MV 2.9%; P=NS). In the MV+SB group, there were significantly longer procedure and fluoroscopy times, higher contrast volumes, and higher rates of procedure-related increases in biomarkers of myocardial injury. A total of 307 patients had a quantitative coronary assessment at the index procedure and after 8 months. The combined angiographic end point of diameter stenosis >50% of main vessel and occlusion of the side branch after 8 months was found in 5.3% in the MV group and 5.1% in the MV+SB group (P=NS). CONCLUSIONS: Independent of stenting strategy, excellent clinical and angiographic results were obtained with percutaneous treatment of de novo coronary artery bifurcation lesions with sirolimus-eluting stents. The simple stenting strategy used in the MV group was associated with reduced procedure and fluoroscopy times and lower rates of procedure-related biomarker elevation. Therefore, this strategy can be recommended as the routine bifurcation stenting technique.

PMID: 17060387 [PubMed - indexed for MEDLINE]Free Article

89.

Eur Heart J. 2006 Nov;27(22):2667-74. Epub 2006 Oct 19.

A systematic review and meta-analysis on the hazards of discontinuing or not adhering to aspirin among 50,279 patients at risk for coronary artery disease.

Biondi-Zoccai GG, Lotrionte M, Agostoni P, Abbate A, Fusaro M, Burzotta F, Testa L, Sheiban I, Sangiorgi G.

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Abstract

AIMS: The role of aspirin in patients with coronary artery disease (CAD) is well established, yet patients happen to discontinue aspirin according to physician's advice or unsupervised. We thus undertook a systematic review to appraise the hazards inherent to aspirin withdrawal or non-compliance in subjects at risk for or with CAD. METHODS AND RESULTS: Electronic databases were systematically searched (updated January 2006). Study designs, patient characteristics, and outcomes were abstracted. Pooled estimates for odds ratios (OR) were computed according to random-effect methods. From the 612 screened studies, six were selected (50,279 patients). One study (31,750 patients) focused on adherence to aspirin therapy in the secondary prevention of CAD, two studies (2594) on aspirin discontinuation in acute CAD, two studies (13,706) on adherence to aspirin therapy before or shortly after coronary artery bypass grafting, and another (2229) on aspirin discontinuation among patients undergoing drug-eluting stenting. Overall, aspirin non-adherence/withdrawal was associated with three-fold higher risk of major adverse cardiac events (OR=3.14 [1.75-5.61], P=0.0001). This risk was magnified in patients with intracoronary stents, as discontinuation of antiplatelet treatment was associated with an even higher risk of adverse events (OR=89.78 [29.90-269.60]). CONCLUSION: Non-compliance or withdrawal of aspirin treatment has ominous prognostic implication in subjects with or at moderate-to-high risk for CAD. Aspirin discontinuation in such patients should be advocated only when bleeding risk clearly overwhelms that of atherothrombotic events.

PMID: 17053008 [PubMed - indexed for MEDLINE]Free Article

Related citations

90.

J Interv Cardiol. 2006 Oct;19(5):422-31.

An overview of the TAXUS Express, paclitaxel-eluting stent clinical trial program.

Lasala JM, Stone GW, Dawkins KD, Serruys PW, Colombo A, Grube E, Koglin J, Ellis S.

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Abstract

Restenosis remains a problem following percutaneous coronary intervention in patients with coronary artery disease. Drug-eluting stents (DES), which combine mechanical and pharmacologic properties, have been shown to prevent or reduce neointimal growth after deployment. This review describes the TAXUS paclitaxel-eluting stent clinical trial expansion program (TAXUS Express, Boston Scientific, Natick, MA). This program comprises the largest data set of randomized controlled trials (RCTs) of DES to date, with over 6,200 patients enrolled since 2000. The program includes treatment of de novo lesions, as well as higher-risk lesion and patient populations. In this review, we discuss the results from the TAXUS family of randomized clinical trials, and compare the findings with data from TAXUS registries. The data from the randomized clinical trials suggest that the paclitaxel-eluting stent provides consistent and durable benefits across multiple lesion and patient types. Evidence from peri-and post-approval registries, where patient populations are more heterogeneous than those eligible and included in the RCTs, corroborate these findings, with overall low rates of cardiac events, including reinterventions.

91.

J Interv Cardiol. 2006 Oct;19(5):405-13.

Overview of pharmacology and clinical trials program with the zotarolimus-eluting endeavor stent.

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Abstract

Despite considerable benefits associated with current drug-eluting stents (DES), continued attention to the safety, efficacy, and deliverability of first-generation DES has led to the development of new antiproliferative agents with alternative stent platforms and different drug carrier systems. Zotarolimus is a recently developed pharmacologic agent with both antiproliferative and anti-inflammatory properties. The Endeavor drug-eluting stent (Medtronic Vascular, Santa Rosa, CA) represents the combination of zotarolimus, a low-profile cobalt alloy stent platform, and a biocompatible phosphorylcholine drug carrier system. At present, four clinical trials examining the safety and efficacy of the Endeavor stent have been performed. Although these studies have enrolled patients with similar clinical and angiographic characteristics, they have differed in trial design and study population size and have been performed across a broad geographic and physician distribution. Despite these differences, the results of these trials demonstrate consistently low rates of angiographic restenosis and repeat revascularization in addition to a favorable safety profile, with no occurrences of late stent thrombosis through 1 year of follow-up. This review describes the pharmacology and design on the Endeavor stent, summarizes results from recent clinical trials evaluating the Endeavor stent, and provides an overview of ongoing and future directions for clinical investigation.

PMID: 17020565 [PubMed - indexed for MEDLINE]

92.

N Engl J Med. 2006 Sep 14;355(11):1105-13.

Paclitaxel-eluting versus uncoated stents in primary percutaneous coronary intervention.

Laarman GJ, Suttorp MJ, Dirksen MT, van Heerebeek L, Kiemeneij F, Slagboom T, van der Wieken LR, Tijssen JG, Rensing BJ, Patterson M.

Department of Interventional Cardiology, Onze Lieve Vrouwe Gasthuis, Amsterdam, The Netherlands. g.j.laarman@olvg.nl

Comment in:

- N Engl J Med. 2006 Dec 7;355(23):2483-4; author reply 2484-6.

- N Engl J Med. 2006 Dec 7;355(23):2484; author reply 2484-6.
- N Engl J Med. 2006 Sep 14;355(11):1169-70.

Comment on:

- N Engl J Med. 2006 Sep 14;355(11):1093-104.

Abstract

BACKGROUND: Drug-eluting coronary-artery stents have been shown to decrease restenosis and therefore the likelihood that additional procedures will be required after percutaneous coronary intervention (PCI). We evaluated the use of a drug-eluting stent in patients undergoing PCI for acute myocardial infarction with ST-segment elevation. METHODS: We randomly assigned 619 patients presenting with an acute myocardial infarction with ST-segment elevation to receive either a paclitaxel-eluting stent or an uncoated stent. The primary end point was a composite of death from cardiac causes, recurrent myocardial infarction, or target-lesion revascularization at 1 year. RESULTS: Baseline clinical and angiographic characteristics in both groups were well matched. There was a trend toward a lower rate of serious adverse events in the paclitaxel-stent group than in the uncoated-stent group (8.8% vs. 12.8%; adjusted relative risk, 0.63; 95% confidence interval, 0.37 to 1.07; P=0.09). A nonsignificant trend was also detected in favor of the paclitaxel-stent group, as compared with the uncoated-stent group, in the rate of death from cardiac causes or recurrent myocardial infarction (5.5% vs. 7.2%, P=0.40) and in the rate of target-lesion revascularization (5.3% vs. 7.8%, P=0.23). The incidence of stent thrombosis during 1 year of follow-up was the same in both groups (1.0%). CONCLUSIONS: Although the use of paclitaxel-eluting stents in acute myocardial infarction with ST-segment elevation reduced the incidence of serious adverse cardiac events at 1 year by 4.0 percentage points, as compared with uncoated stents, the difference was not statistically significant. (Current Controlled Trials number, ISRCTN65027270 [controlled-trials.com].).

PMID: 16971717 [PubMed - indexed for MEDLINE]Free Article

93.

N Engl J Med. 2006 Sep 14;355(11):1093-104.

Sirolimus-eluting versus uncoated stents in acute myocardial infarction.

Spaulding C, Henry P, Teiger E, Beatt K, Bramucci E, Carrié D, Slama MS, Merkely B, Erglis A, Margheri M, Varenne O, Cebrian A, Stoll HP, Snead DB, Bode C; TYPHOON Investigators.

Assistance Publique-Hôpitaux de Paris (AP-HP) Cochin Hospital, Paris 5 Medical School Rene Descartes University and INSERM U780, Paris, France. christian.spaulding@cch.ap-hop-paris.fr

Comment in:

- N Engl J Med. 2006 Dec 7;355(23):2483; author reply 2484-6.
- N Engl J Med. 2006 Sep 14;355(11):1105-13.
- N Engl J Med. 2006 Sep 14;355(11):1169-70.
- N Engl J Med. 2006 Dec 7;355(23):2484; author reply 2484-6.
- N Engl J Med. 2006 Dec 7;355(23):2483-4; author reply 2484-6.

Abstract

BACKGROUND: Sirolimus-eluting stents reduce rates of restenosis and reintervention, as compared with uncoated stents. Data are limited regarding the safety and efficacy of such stents in primary percutaneous coronary intervention (PCI) for acute myocardial infarction with ST-segment elevation. METHODS: We performed a single-blind, multicenter, prospectively randomized trial to compare sirolimus-eluting stents with uncoated stents in primary PCI for acute myocardial infarction with ST-segment elevation. The trial included 712 patients at 48 medical centers. The primary end point was target-vessel failure at 1 year after the procedure, defined as target-vessel-related death, recurrent myocardial infarction, or target-vessel revascularization. A follow-up angiographic substudy was performed at 8 months among 174 patients from selected centers. RESULTS: The rate of the primary end point was significantly lower in the sirolimus-stent group than in the uncoated-stent group (7.3% vs. 14.3%, P=0.004). This reduction was driven by a decrease in the rate of target-vessel revascularization (5.6% and 13.4%, respectively; P<0.001). There was no significant difference between the two groups in the rate of death (2.3% and 2.2%, respectively; P=1.00), reinfarction (1.1% and 1.4%, respectively; P=1.00), or stent thrombosis (3.4% and 3.6%, respectively; P=1.00). The degree of neointimal proliferation, as assessed by the mean (+/-SD) in-stent late luminal loss, was significantly lower in the sirolimus-stent group (0.14+/-0.49 mm, vs. 0.83+/-0.52 mm in the uncoated stent group; P<0.001). CONCLUSIONS: Among selected patients with acute myocardial infarction, the use of sirolimus-eluting

stents significantly reduced the rate of target-vessel revascularization at 1 year. (ClinicalTrials.gov number, NCT00232830 [ClinicalTrials.gov].). Copyright 2006 Massachusetts Medical Society.

94.

Radiother Oncol. 2007 Jan;82(1):18-23. Epub 2006 Sep 12.

Randomized comparison between intracoronary beta-radiation brachytherapy and implantation of paclitaxel-eluting stents for the treatment of diffuse in-stent restenosis.

Schukro C, Syeda B, Kirisits C, Schmid R, Pichler P, Pokrajac B, Lang I, Pötter R, Glogar D.

Department of Internal Medicine II, Division of Cardiology, Medical University of Vienna, Vienna, Austria. christoph.schukro@meduniwien.ac.at

Comment in:

- Radiother Oncol. 2007 Jan;82(1):1-4.

Abstract

BACKGROUND AND PURPOSE: Intracoronary brachytherapy was the primary therapeutic option for the treatment of in-stent restenosis (ISR) during the last years. Especially for the treatment of diffuse ISR (lesions >10mm), beta-source brachytherapy was significantly superior to singular balloon angioplasty. Despite lacking clinical database, the implantation of drug eluting stents recently became a common procedure for the treatment of ISR. This randomized trial aimed to compare the efficacy of beta-brachytherapy with beta-radioisotopes (90)Sr/(90)Y and paclitaxel-eluting stent implantation for the treatment of diffuse ISR. MATERIAL AND METHODS: Thirty-seven patients with diffuse ISR were randomly assigned to beta-brachytherapy after balloon angioplasty (Beta-Cath in 17 patients) or paclitaxel-eluting stent implantation (Taxus-Express2 in 20 patients). Six-month clinical follow-up was obtained for all patients, while angiographic follow-up was available for 30 patients. RESULTS: Binary ISR (restenosis >50%) within target segment was observed in three patients treated with Beta-Cath, of which one needed target segment revascularisation for recurrent ISR, whereas no significant restenosis occurred in the patients treated with Taxus-Express2 (P=0.037). No further major adverse cardiac (target segment revascularisation, myocardial infarction, death) was found in either group (P=NS). Stent

implantation was the more time-saving (31+/-11 min versus 60+/-23 min, P<0.001) procedure. CONCLUSIONS: Although this trial revealed a significant reduction of binary restenosis in the Taxus-Express2 arm, we found no difference in clinical outcome after implantation of paclitaxel-eluting stents for the treatment of diffuse ISR when compared to beta-brachytherapy.

PMID: 16971011 [PubMed - indexed for MEDLINE]

95.

Am J Cardiol. 2006 Aug 15;98(4):443-6. Epub 2006 Jun 23.

Angiographic results of the first human experience with the Biolimus A9 drug-eluting stent for de novo coronary lesions.

Costa RA, Lansky AJ, Abizaid A, Müeller R, Tsuchiya Y, Mori K, Cristea E, Leon MB, Sousa JE, Schmidt T, Hauptmann KE, Grube E.

The Cardiovascular Research Foundation and Columbia University Medical Center, New York, New York, USA.

Abstract

This report describes angiographic findings of the first-in-human evaluation of the Biolimus A9 drug-eluting stent (Biolimus stent) in the treatment of noncomplex coronary lesions. In total, 120 patients with 122 de novo coronary lesions (2.75- to 4.00-mm vessels, < or = 24-mm lesion length) were prospectively randomized in a 2:1 ratio to receive the Biolimus stent (n = 80, 82 lesions) or the control uncoated stent (n = 40). Baseline lesion and angiographic characteristics were similar between groups. At 6-month follow-up, late lumen loss was significantly decreased with the Biolimus stent in the stent (0.26 +/- 0.43 vs 0.74 +/- 0.45 mm, p < 0.001) and in the segment (0.14 +/- 0.45 vs 0.40 +/- 0.41 mm, p = 0.004). In-stent restenosis was 3.9% in the Biolimus stent group versus 7.7% in the control group (p = 0.40). There was no exaggerated hyperplasia at the proximal and/or distal edge of the stent.

PMID: 16893694 [PubMed - indexed for MEDLINE]

96.

Circulation. 2006 Jul 4;114(1 Suppl):I145-51.

Differential effect of intracoronary infusion of mobilized peripheral blood stem cells by granulocyte colony-stimulating factor on left ventricular function and remodeling in patients with acute myocardial infarction versus old myocardial infarction: the MAGIC Cell-3-DES randomized, controlled trial.

Kang HJ, Lee HY, Na SH, Chang SA, Park KW, Kim HK, Kim SY, Chang HJ, Lee W, Kang WJ, Koo BK, Kim YJ, Lee DS, Sohn DW, Han KS, Oh BH, Park YB, Kim HS.

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Abstract

BACKGROUND: The efficacy of intracoronary infusion of granulocyte colony-stimulating factor (G-CSF) mobilized peripheral blood stem cells (PBSCs) has not been compared between patients with acute (AMI) versus old myocardial infarction (OMI). In addition, the potential risk of restenosis associated with G-CSF-based stem cell therapy has not been evaluated in the setting of drug eluting stent (DES) implantation. METHODS AND RESULTS: We randomly allocated 96 patients with myocardial infarction who underwent coronary revascularization with DES for the culprit lesion into 4 groups. Eighty-two patients completed 6-month follow-up; AMI cell infusion (n=25), AMI control (n=25), OMI cell infusion (n=16), and OMI control group (n=16). In cell infusion groups, PBSCs were mobilized by G-CSF for 3 days and delivered to infarcted myocardium via intracoronary infusion. The AMI cell infusion group showed a significant additive improvement in left ventricular ejection fraction (LVEF) and remodeling compared with controls (change of LVEF: +5.1+/-9.1% versus -0.2+/-8.6%, P<0.05; change of end-systolic volume: -5.4+/-17.0 mL versus 6.5+/-21.9 mL, P<0.05). In OMI patients, however, there was no significant change of LVEF and ventricular remodeling in spite of significant improvement of coronary flow reserve after cell infusion. G-CSF-based cell therapy did not aggravate neointimal growth with DES implantation. CONCLUSIONS: Intracoronary infusion of mobilized PBSCs with G-CSF improves LVEF and remodeling in patients with AMI but is less definite in patients with OMI. G-CSF-based stem cell therapy with DES implantation is both feasible and safe, eliminating any potential for restenosis.

PMID: 16820564 [PubMed - indexed for MEDLINE]Free Article

97.

J Am Coll Cardiol. 2006 Jun 6;47(11):2152-60.

A randomized comparison of sirolimus-eluting stent with balloon angioplasty in patients with in-stent restenosis: results of the Restenosis Intrastent: Balloon Angioplasty Versus Elective Sirolimus-Eluting Stenting (RIBS-II) trial.

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Comment in:

- J Am Coll Cardiol. 2006 Jun 6;47(11):2161-3.

Abstract

OBJECTIVES: We sought to assess the effectiveness of sirolimus-eluting stents (SES) in patients with in-stent restenosis (ISR). BACKGROUND: Treatment of patients with ISR remains a challenge. METHODS: The Restenosis Intrastent: Balloon Angioplasty Versus Elective Sirolimus-Eluting Stenting (RIBS-II) study is a multicenter randomized trial conducted in 150 patients with ISR (76 allocated to SES and 74 to balloon angioplasty [BA]). The primary end point was recurrent restenosis rate at nine months. Secondary end points included prespecified subgroup analysis, lumen volume on intravascular ultrasound (IVUS), and a composite of major clinical events at one year. RESULTS: Angiographic success was obtained in all patients. At 9-month angiographic follow-up (96% of eligible patients) minimal lumen diameter was larger (2.52 mm [interquartile range (IQR) 2.09 to 2.81] vs. 1.54 mm [IQR 0.91 to 2.05]; $p < 0.001$) and recurrent restenosis rate was lower (11% vs. 39%; $p < 0.001$) in the SES group. Prespecified subgroup analyses were consistent with the main outcome measure. Lumen volume on IVUS at 9 months was also larger (279 mm3 [IQR 227 to 300] vs. 197 mm3 [IQR 177 to 230]; $p < 0.001$) in the SES group. At one-year clinical follow-up (100% of patients), the event-free survival (freedom from death, myocardial infarction, and target vessel revascularization) was significantly improved in the SES group (88% vs. 69%; $p < 0.004$) as the result of a lower requirement for target vessel revascularization (11% vs. 30%; $p < 0.003$). CONCLUSIONS: In patients with ISR, the use of SES provides superior long-term clinical, angiographic, and IVUS outcome than BA treatment.

PMID: 16750678 [PubMed - indexed for MEDLINE]

98.

Am J Cardiol. 2006 Feb 15;97(4):494-8. Epub 2006 Jan 4.

Comparison between sirolimus- and paclitaxel-eluting stent in T-cell subsets redistribution.

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Abstract

We sought to investigate the effects of 2 different coronary drug-eluting stents on the distribution of central or effector memory T cells circulating in the coronary sinus of patients with coronary artery disease who underwent percutaneous coronary revascularization. We randomly assigned 43 patients (mean age 65.4 +/- 4.3 years; 34 men) presenting with stable coronary disease and angiographically proved stenosis of the left anterior descending artery to treatment with sirolimus- or paclitaxel-eluting stents. Heparinized blood samples were obtained from the coronary sinus before and 20 minutes after stent implantation. Analysis of surface phenotype was performed by 4-color flow cytometry, and data are expressed as the percentage of positive cells. The percentages of CD8+ and CD4+ effector memory T cells, as defined by the CD3+CD45RO+CD27- phenotype, were significantly reduced in patients who received a sirolimus-eluting stent compared with the basal values. Conversely, the percentages of CD8+, but not CD4+, central memory T cells (CD3+CD45RO+CD27+) were increased in the same treatment group after the revascularization procedure. No changes in the percentages of memory T-cell populations in the paclitaxel-eluting stent group were observed. These findings show that sirolimus-eluting stents rapidly induced a redistribution of memory T lymphocytes, with a significant decrease of proinflammatory effector memory T cells circulating within the coronary sinus.

PMID: 16461044 [PubMed - indexed for MEDLINE]

99.

J Interv Cardiol. 2005 Dec;18(6):447-53.

Drug-eluting stents for interventional revascularization of coronary multivessel disease.

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Abstract

The treatment of coronary artery disease has changed over the past 35 years since the introduction of coronary artery bypass surgery in 1968. Percutaneous coronary intervention, introduced in 1977 with balloon angioplasty, was accelerated by the establishment of elective stent placement in 1994, together with the development of suitable antiplatelet regimes. In 2002, DES were made commercially available, following the results of clinical trials in single lesions. A meta-analysis of four randomized clinical trials comparing bare stents to bypass surgery for multivessel disease conducted in the 1990s demonstrate no mortality difference at 1 year. Similar 5-year outcomes have been reported by the ARTS trial. These trials, however, showed that repeat revascularization was much higher in the stent arm, due to restenosis. Various single center (RESEARCH, T-SEARCH) and multicenter (ARTS II) registries have consistently showed a low need for repeat intervention in patients with multivessel disease with the use of DES. Three major trials comparing DES against bypass surgery are ongoing or about to start and will determine the optimum revascularization therapy in multivessel disease. The recently commenced SYNTAX randomized trial will enroll only three-vessel or left main disease, while the upcoming FREEDOM and ongoing CARDia trial will specifically enroll diabetic patients only with multivessel disease. Results for these trials are expected in 2006-2007 at the earliest. (J Interven Cardiol 2005;18:447-453).

PMID: 16336425 [PubMed - indexed for MEDLINE]

100.

Circulation. 2005 Nov 22;112(21):3306-13. Epub 2005 Nov 14.

Clinical efficacy of polymer-based paclitaxel-eluting stents in the treatment of complex, long coronary artery lesions from a multicenter, randomized trial: support for the use of drug-eluting stents in contemporary clinical practice.

Dawkins KD, Grube E, Guagliumi G, Banning AP, Zmudka K, Colombo A, Thuesen L, Hauptman K, Marco J, Wijns W, Popma JJ, Koglin J, Russell ME; TAXUS VI Investigators.

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Comment in:

- Evid Based Cardiovasc Med. 2006 Mar;10(1):49-51.

Abstract

BACKGROUND: Intracoronary polymer-based stent delivery of paclitaxel has been shown to be effective in reducing restenosis in simple coronary lesions, but the evidence base for contemporary use in longer, more complex coronary stenoses is lacking. METHODS AND RESULTS: TAXUS VI is a prospective, multicenter, double-blind, randomized trial assessing clinical and angiographic outcomes of the TAXUS Moderate Release paclitaxel-eluting stent in the treatment of long, complex coronary artery lesions. Four hundred forty-eight patients at 44 sites were randomized (1:1) between a drug-eluting TAXUS Express2 and an uncoated Express2 control stent. Per protocol, the 9-month follow-up included an angiographic reevaluation in all patients. The primary end point was the rate of target-vessel revascularization 9 months after the study procedure; secondary end points included the rate of target-lesion revascularization and binary restenosis at follow-up. Mean lesion length in the study was 20.6 mm, with a mean stent-covered length of 33.4 mm. Of all lesions, 55.6% were classified as complex lesions (type C of the AHA/ACC classification). At 9 months, target-vessel revascularization was 9.1% in the TAXUS group and 19.4% in the control group (P=0.0027; relative reduction, 53%). Target-lesion revascularization was reduced from 18.9% to 6.8%, respectively (P=0.0001). The incidence of major adverse cardiac events was similar in the 2 groups, 16.4% and 22.5% in TAXUS and control, respectively (P=0.12), including comparable rates for acute myocardial infarction. Binary restenosis in the stented area was reduced from 32.9% in the control group to 9.1% in the TAXUS patients (P<0.0001). CONCLUSIONS: The finding that the TAXUS Moderate Release stent system is safe and effective in the treatment of long, complex coronary artery lesions provides the evidence base for the more widespread use of drug-eluting stents in contemporary clinical practice.

101.

Am J Cardiol. 2005 Nov 15;96(10):1404-7. Epub 2005 Sep 29.

Impact of asymmetric stent expansion on neointimal hyperplasia following sirolimus-eluting stent implantation.

Kaneda H, Ako J, Honda Y, Terashima M, Morino Y, Yock PG, Popma JJ, Leon MB, Moses JW, Fitzgerald PJ.

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Abstract

To assess whether asymmetric stent expansion affects suppression of neointimal hyperplasia after sirolimus-eluting stent implantation, 64 patients in the SIRolImUS-coated Bx Velocity stent trial who underwent single 18-mm stent implantation and 3-dimensional intravascular ultrasonography at 8-month follow-up were enrolled. To assess the longitudinal stent asymmetric expansion, 2 cross sections with a maximal/minimal stent area were chosen in each patient. To assess for tomographic stent asymmetric expansion, stent eccentricity was determined by dividing the minimum stent diameter by the maximum stent diameter. At the 2 cross sections with a maximal/minimal stent area, a sirolimus-eluting stent reduced neointimal hyperplasia significantly with no interaction between the treatment and stent areas. A sirolimus-eluting stent also significantly reduced neointimal hyperplasia in the concentric and eccentric stent groups.

102.

Am J Cardiol. 2005 Nov 1;96(9):1237-41. Epub 2005 Sep 2.

Impact of intravascular ultrasound lesion characteristics on neointimal hyperplasia following sirolimus-eluting stent implantation.

Kaneda H, Koizumi T, Ako J, Terashima M, Morino Y, Honda Y, Yock PG, Leon MB, Moses JW, Fitzgerald PJ.

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Abstract

The effect of lesion characteristics on neointimal hyperplasia after sirolimus-eluting stent implantation was examined in 45 patients who underwent successful preinterventional intravascular ultrasound. There were no differences in neointimal hyperplasia between the moderate/severe calcified lesion group

(calcium arc >120 degrees) and the non/mild calcified lesion group or between the positive vessel remodeling group (external elastic membrane area at the minimal lumen area site larger than that at the proximal reference site) and negative vessel remodeling group. No correlation between preinterventional plaque burden and neointimal hyperplasia was found. In patients who have coronary artery disease, sirolimus-eluting stents continue to demonstrate striking suppression of neointimal proliferation, irrespective of lesion characteristics previously associated with greater restenotic risk.


103.

Heart. 2006 May;92(5):641-9. Epub 2005 Oct 10.

Drug eluting stents: an updated meta-analysis of randomised controlled trials.

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Abstract

OBJECTIVE: To confirm the overall benefit of drug eluting stents (DES), to evaluate the effect of different DES, and to assess the global safety of DES compared with bare stents through a meta-analysis of randomised controlled trials. METHODS: Randomised controlled trials comparing sirolimus and derivates or paclitaxel and derivates eluting stents versus bare stents. Binary restenosis and major adverse cardiac events (MACE) were chosen as primary end points. Death, Q wave myocardial infarction (MI), and stent thrombosis up to 12 months' follow up were also analysed. RESULTS: MACE overall occurrence was highly reduced with DES from 19.9% to 10.1% (odds ratio (OR) 0.46, 95% confidence interval (CI) 0.41 to 0.52, $p < 0.001$). A significant heterogeneity ($p < 0.001$) was found between subgroups according to the drug: MACE OR was 0.28 (95% CI 0.22 to 0.35) in the sirolimus subgroup and 0.62 (95% CI 0.53 to 0.73) in the paclitaxel subgroup. Restenosis was also highly reduced from 31.7% with bare stents to 10.5% with DES (OR 0.25, 95% CI 0.22 to 0.29, $p < 0.001$) with a similar heterogeneity between subgroups. Mortality, Q wave MI, and stent thrombosis were not significantly different between DES and control group, whereas Q wave MI and stent thrombosis tended to be more frequent with paclitaxel. CONCLUSION: This meta-analysis confirms the overall benefit of DES on restenosis and MACE with significant heterogeneity between drugs, suggesting higher efficacy

of sirolimus eluting stents. Additional data with longer follow up and in high risk populations are needed to clarify issues on stent thrombosis.

 104.

Circulation. 2005 Oct 4;112(14):2175-83.

Randomized comparison of sirolimus-eluting stent versus standard stent for percutaneous coronary revascularization in diabetic patients: the diabetes and sirolimus-eluting stent (DIABETES) trial.

Sabaté M, Jiménez-Quevedo P, Angiolillo DJ, Gómez-Hospital JA, Alfonso F, Hernández-Antolín R, Goicolea J, Bañuelos C, Escaned J, Moreno R, Fernández C, Fernández-Avilés F, Macaya C; DIABETES Investigators.

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Abstract

BACKGROUND: Outcomes after percutaneous coronary interventions in diabetic patients are shadowed by the increased rate of recurrence compared with nondiabetic patients. METHODS AND RESULTS: We conducted a multicenter, randomized trial to demonstrate the efficacy of sirolimus-eluting stents compared with standard stents to prevent restenosis in diabetic patients with de novo lesions in native coronary arteries. The primary end point of the trial was in-segment late lumen loss as assessed by quantitative coronary angiography at 9-month follow-up. The trial was stratified by diabetes treatment status. One hundred sixty patients were randomized to sirolimus-eluting stents (80 patients; 111 lesions) or standard stent implantation (80 patients; 110 lesions). On average, reference diameter was 2.34+/-0.6 mm, lesion length was 15.0+/-8 mm, and 13.1% of lesions were chronic total occlusions. In-segment late lumen loss was reduced from 0.47+/-0.5 mm for standard stents to 0.06+/-0.4 mm for sirolimus stents (P<0.001). Target-lesion revascularization and major adverse cardiac event rates were significantly lower in the sirolimus group (31.3% versus 7.3% and 36.3% versus 11.3%, respectively; both P<0.001). Non-insulin- and insulin-requiring patients demonstrated similar reductions in angiographic and clinical parameters of restenosis after sirolimus-eluting stent implantation. During the 9-month follow-up, stent thrombosis occurred in 2 patients after standard stent implantation. Conversely, this phenomenon was not seen in the sirolimus stent group. CONCLUSIONS: This randomized trial

demonstrated that sirolimus stent implantation is safe and efficacious in reducing both angiographic and clinical parameters of restenosis compared with standard stents in diabetic patients with de novo coronary stenoses.

 105.

Am J Cardiol. 2005 Sep 1;96(5):664-7.

17-beta-estradiol eluting stent versus phosphorylcholine-coated stent for the treatment of native coronary artery disease.

Airoldi F, Di Mario C, Ribichini F, Presbitero P, Sganzerla P, Ferrero V, Vassanelli C, Briguori C, Carlino M, Montorfano M, Biondi-Zoccai GG, Chieffo A, Ferrari A, Colombo A.

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Abstract

In this study we randomly compared the estradiol eluting stent (17-beta-E) with phosphorylcholine (PC)-coated stents in native coronary arteries. The incidence of angiographic restenosis was 23% in the 17-beta-E group and 31% in the PC group (p = 0.34). The major adverse cardiovascular event rates were also similar in the 2 groups (17% in the 17-beta-E group vs 22% in the PC group, p = 0.47). The mid-term clinical and angiographic outcomes did not indicate superiority of the 17-beta-E eluting stent over the control PC stent.