

ISCHAEMIC HEART DISEASE

TRIALS

NUMBER OF PARTICIPANTS	NUMBER OF WOMEN	PERCENTAGE OF WOMEN	MEAN AGE	MEAN FOLLOW-UP (YEARS)	TRIALS WITH ANALYSIS BY GENDER N, (%)
90,400	24,756	27.3%	62.6	0.96	5/13 (38.4%)

TRIAL	YEAR	POPULATION	AGE	N° OF SUBJECTS	FOLLOW UP	TREATMENT	DESCRIPTION OF END-POINT	PRIMARY END-POINT	PRIMARY END-POINT HR	NOTES
		(Country)	mean ± sd, range	TOTAL (WOMEN n,%)	DURATION			TOTAL (WOMEN n,%) (MEN n,%)	(CI) P (WOMEN) (MEN)	
ASSENT-4 PCI (Van de Werf et al ⁹³)	FEB 2006	Patient with ST-segment elevation acute myocardial infarction (STEMI) scheduled to undergo primary PCI (International with significant European component)	61±12.1 PCI+Tenecteplase; 60±12.0 PCI alone age ≥18 years	TOTAL: 1667 (WOMEN:386, 23%) (MEN: 1281)	90 Days	PCI+Tenecteplase versus PCI alone	Death, congestive heart failure, shock, within 90 days	PCI+Tenecteplase TOTAL 151, 18.6% (WOMEN 58/190, 30.5%) (MEN 93/620, 15.0%) PCI alone TOTAL: 110, 13.4% (WOMEN: 29/182, 15.9%) (MEN: 81/637, 12.7%)	TOTAL Relative Risk = 1.39 [95% CI: 1.11-1.74] WOMEN Relative Risk = 1.92 [95% CI: 1.29-2.85] MEN Relative Risk= 1.18 [95% CI: 0.89-1.56]	Tenecteplase was associated with more major adverse events particularly in women, but the interaction was not significant

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CLARITY-TIMI 28 (Scirica et al ⁹⁴)	JULY 2006	Patients with ST-segment elevation myocardial infarction (STEMI) undergoing fibrinolysis (International with significant European component)	57.6 Clopidogrel; 57.3 Placebo; age >65 years	Total: 3491, patients with Electrocardiograms valid for interpretation : 2431 (Women 462, 19%) (Men 1969)	30 days	Clopidogrel vs placebo	Complete STResolution at 90 min, in-hospital death or recurrent MI, epicardial flow (TIMI flow grade 2 or 3) at late angiography	Complete STRes at 90 min Clopidogrel 38.4% Placebo 36.6% TIMI flow grade 3 pt with complete STRes: Placebo 434, 66.4% Clopidogrel 474, 80.2% in-hospital death or recurrent MI pt with partial STRes: Placebo 426, 6.6% Clopidogrel 395, 2% pt with complete STRes: Placebo 434, 5.1% Clopidogrel 474, 2.5%	OR _{ADJUSTED} = 1.08 [95% CI: 0.91 -1.29] OR _{ADJUSTED} = 2.0 [95% CI: 1.5 -2.8] P<0.001 OR _{ADJUSTED} = 0.30 [95% CI: 0.13 - 0.67] P= 0.003 OR _{ADJUSTED} = 0.49 [95% CI: 0.24 - 1.02] P= 0.056	Results by gender not reported

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PRINCIPLE-TIMI 44 (Wiviott et al ⁹⁵)	DEC 2007	Patients undergoing cardiac catheterization for planned percutaneous coronary intervention (International with significant European component)	Prasugrel 64; Clopidogrel 163.8; age: >18 years	TOTAL. 201 (WOMEN: 51, 25%) (MEN 150)	29 days	Loading-dose: prasugrel 60 mg vs clopidogrel 600 mg; maintenance-dose: prasugrel 10 mg vs clopidogrel 150 mg	For the loading-dose phase: IPA with 20 µmol/L ADP at 6 hours; for the maintenance-dose phase: IPA after 14 days	Loading-dose phase: Prasugrel 74.8±13.0%; clopidogrel 31.8± 21.1%; maintenance-dose phase: Prasugrel 61.3±17.8%; clopidogrel 46.1± 21.3%	LS mean difference 43.2% [95% CI: 38.0- 48.4] P< 0.0001 LS mean difference 14.9% [95% CI: 10.6-19.3] P< 0.0001	Results by gender not reported
PPCI (Kukreja et al ⁹⁶)	OCT 2008	Patients undergoing primary percutaneous coronary intervention (PCI) for a de novo lesion (Netherlands)	59.1± 11.9	TOTAL: 1738 (WOMEN: 374, 21.5%) (MEN: 1364)	median duration 1185 days (746 to 1675)	3 sequential consecutive cohorts of bare metal stents (BMS), sirolimus-eluting (SES) or paclitaxel-eluting stents (PES)	3 year All-cause death, nonfatal myocardial infarction, target vessel revascularization	Death BMS: 16.4% SES: 11.4% PES: 12.9% Composite MACE BMS: 25.0% SES: 17.8% PES: 21.5%	Death propensity score-adjusted SES vs BMS: adjusted HR = 0.63 [95% CI: 0.33-1.18] SES vs PES: adjusted HR= 0.71 [95% CI: 0.40-1.26] Composite MACE propensity score-adjusted SES vs PES adjusted HR= 0.62 [95% CI: 0.40-0.96]	Results by gender not reported

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Analysis from the TRITON-TIMI 38 (Murphy et al ⁹⁸)	OCT 2008	Patient with acute coronary syndrome undergoing planned PCI (International trial with significant European component)	63 Prasugrel; 62 Clopidogrel	TOTAL: 13608 (WOMEN: 3523, 26%) (MEN:10085)	Minimum 6 months, maximum 15 months	Prasugrel versus Clopidogrel	Recurrence of CV death or MI or stroke	3.7% Prasugrel; 7.1% Clopidogrel (WOMEN 13.6% Prasugrel, 20.5% Clopidogrel) (MEN 9.7% Prasugrel, 13.6 Clopidogrel)	HR = 0.46 [95%CI: 0.25-0.82] P= 0.008	No significant interactions by subgroup, including gender Women tended to have a higher incidence of subsequent event but the greater efficacy of prasugrel was observed in both gender

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TRITON-TIMI 38 (Montalescot et al ⁹⁹)	FEB 2009	Patients with ST-elevation myocardial infarction (STEMI) (International with significant European component)	58 Prasugrel; 59 Clopidogrel	TOTAL: 3534 (WOMEN 799, 22,6%) (MEN 2735)	15 months	Prasugrel 60 mg loading, 10 mg maintenance versus clopidogrel 300 mg loading, 75 mg maintenance	Cardiovascular death, non-fatal myocardial infarction, non-fatal stroke at 30 days to 15 months.	At 30 days: 115, 6.5% Prasugrel, 166, 9.5% Clopidogrel; At 15 months: 174, 10.0% Prasugrel, 216, 12.4% Clopidogrel	At 30 days: HR= 0.68 [95% CI: 0.54–0.87] P =0.0017 At 15 months: HR = 0.79 [95% CI: 0.65–0.97] P=0.0221	Results by gender not reported

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A substudy of the OASIS 5 and a meta-analysis of FRISC II, RITA 3, ICTUS, OASIS 5 TACTICS TIMI-18 (Swahn et al ¹²⁹)	Advance Access published FEB 2009	women with non-ST-elevation acute coronary syndromes (International with significant European component)	OASIS 5 substudy: Routine invasive 68.2+9.2 Selective invasive 67.8+8.8 age ≥21 years	OASIS 5 substudy: WOMEN 184 meta-analysis: TOTAL: 7871 (WOMEN 2692, 34.2%) (MEN 5179)	OASIS 5 substudy : 2 years meta-analysis: 1-year	OASIS 5 substudy: a routine coronary angiography versus a selective invasive strategy with coronary angiography only if they experienced symptoms or signs of severe ischaemia.	OASIS 5 substudy: death, MI, or stroke at 2 years meta-analysis: 1-year death, MI	<i>OASIS 5 substudy:</i> Routine invasive 19 (21.0%) Selective Invasive 14 (15.4%) <i>(deaths at 1 year</i> Routine invasive 8.8% Selective invasive 1.1% <i>major bleeding at 30 days</i> Routine invasive 8.8 % Selective invasive 1.1%)) <i>Meta-analysis:</i> <i>Death, MI :</i> WOMEN Routine Invasive 10.4% Selective Invasive 9.1% MEN Routine invasive 9.8% Selective Invasive 12.1% <i>Death:</i> WOMEN Routine invasive 4.3% Selective Invasive 2.9% MEN Routine invasive: 2.7% Selective Invasive:3.9%	HR= 1.46 [95% CI: 0.73–2.94] <i>(Deaths After 1 Year</i> HR = 9.01 [95% CI 1.11–72.90] <i>major bleeding at 30 days</i> HR = 11.45 [95% CI: 1.43–91.96] <i>Meta-analysis:</i> OR = 1.18 [95% CI: 0.92–1.53] OR=0.78 [95% CI: 0.66–0.93] OR =1.51 [95% CI: 1.00–2.29] OR = 0.70 [95% CI: 0.51–0.96]	No benefit of an early invasive strategy with greater mortality in women with ACS

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PCI-CURE (Jolly et al ¹⁰⁰)	APR 2009	Patients with acute coronary syndromes undergoing PCI (International with 48.8% Western Europe, 11.2% Eastern Europe, 21.4% Canada/USA, 10.4% Latin America, 8.0% Other)	Low dose 62.2±10.9 Medium dose 61.0 ±10.6 High dose 61.1±11.3	TOTAL: 2658 (WOMEN 804, 30.2%) (MEN 1854)	Mean follow-up 8 months	3 aspirin dose groups: ≥200 mg (high) 101–199 mg (moderate) ≤100 mg (low).	Cardiovascular death, myocardial infarction, or stroke at 30 days and at long term follow-up	At 30 days: 43 (4.1%) low 17 (3.2%) moderate 43 (4.0%) high long-term follow-up: 75 (7.1%) low 40 (7.4%) moderate 91 (8.6%) high	At 30 days: HR = 0.99 [95% CI: 0.65–1.51] High vs. low dose HR = 0.77 [95% CI: 0.44–1.35] Moderate vs. low dose long-term follow-up: HR = 1.21 [95% CI: 0.89–1.64] High vs. low dose HR = 1.04 [95% CI: 0.71–1.52] Moderate vs. low dose	Results by gender not reported

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EASY Gender subanalysis (Tizon-Marcos et al ¹⁰¹)	APR 2009	Patients with acute coronary syndrome undergoing transradial PCI	Women: 62.5±11.0 Men: 59.7±10.0;	TOTAL: 1348 (WOMEN. 298, 22%) (MEN: 1050)	30 days, 6 months, and 12 months.	Bolus-only abciximab to overnight hospitalization versus bolus followed by 12-hour infusion of abciximab after uncomplicated transradial coronary stenting.	Major adverse cardiac events including death, myocardial infarction, target vessel revascularization, major bleeding and local hematomas were evaluated at 30 days, 6 months, and 12 months	At 30 days: WOMEN 10 (3.4%) MEN 41 (3.9%) at 6 months: WOMEN 34 (11.5%) MEN 82 (7.8%) at 12 months: WOMEN 42 (14.1%) MEN 132(12.6%)	At 30 days: P = 0.86 at 6 months: P = 0.06 at 12 months P = 0.49	Women tended to have more events than men at 6 months although the difference is not significant

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Analysis from ACUITY (Ebrahimi et al ¹⁰²)	MAY 2009	Patients with NSTEMI-ACS undergoing early invasive management who received CABG	Clopidogrel Before CABG Median 65 (range 33–87) No Clopidogrel Before CABG Median 64 (range 35–90)	Of 13819 pt 1539 (11.1%) underwent CABG (WOMEN 353, 22.9%) (MEN 1186)	1 year	Clopidogrel-exposed patients before CABG vs non-exposed	Ischemic events (death, myocardial infarction, or unplanned revascularization)	30-day Clopidogrel before CABG: 98 (12.7%) No Clopidogrel before CABG: 129 (17.3%) 1-year Clopidogrel before CABG: 142 (18.4%) No Clopidogrel before CABG: 160 (21.4%)	P= 0.001 P = 0.14 Non-CABG-related major bleeding (3.4% vs. 3.2%, p= 0.87) post-CABG major bleeding (50.3% vs. 50.9%, p =0.83)	Results by gender not reported

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SCAAR (James et al ¹⁰⁴)	MAY 2009	Patients who had received a coronary stent (Sweden)	66.2±11.0 Bare-Metal Stent 65.5±10.7 Drug-Eluting Stent	TOTAL: 47967 (WOMEN: 13344, 27.8%) (MEN: 34623)	1 to 5 years of follow-up (mean 2.7)	Drug eluting coronary stent versus bare-metal stent	Death or myocardial infarction	Death: Total 2380 MI: total 3198 no significant difference in outcome among subgroups	RR = 0.96 [95% CI: 0.89-1.03]	Results by gender not reported
EARLY ACS (Giugliano et al ¹⁰⁵)	MAY 2009	Patients who had acute coronary syndromes without ST-segment elevation and who were assigned to an invasive strategy. (International: Western Europe 40.3% Eastern Europe 10.8% North America 30.7% Middle East, Africa, or Asia-Pacific 18.15%)	Early eptifibatide: 67.4; delayed eptifibatide: 67.8	TOTAL: 9406 (WOMEN 3009, 32%) (MEN 6397)	30 days	Early eptifibatide (two boluses, each containing 180 µg per kilogram of body weight, administered 10 minutes apart, and a standard infusion ≥12 hours before angiography) versus a matching placebo infusion with provisional use of eptifibatide after angiography (delayed eptifibatide).	Composite of death, myocardial infarction, recurrent ischemia requiring urgent revascularization, or the occurrence of a thrombotic complication during percutaneous coronary intervention (thrombotic bailout) at 96 hours.	Early eptifibatide group: 439 (9.3%); delayed-eptifibatide group: 469 (10.0%) WOMEN Early eptifibatide group 9.7% delayed-eptifibatide 10.4% MEN Early eptifibatide group 9.1% delayed-eptifibatide 9.8%	OR = 0.92 [95% CI: 0.80 -1.06] P = 0.23 Death/myocardial infarction (secondary endpoint) WOMEN Early eptifibatide group 10.7% delayed-eptifibatide 13.0% MEN Early eptifibatide group 11.4% delayed-eptifibatide 12.0%	No significant difference between early or delayed eptifibatide in the primary endpoint in both gender. Lower incidence of Death/MI (secondary endpoint) with early intervention in women than in men (p interaction =0.046)

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SYNTAX (Serruys et al ¹⁰⁶)	MAR 2009	International trial conducted in 17 countries in Europe and the United States in patients with three-vessel or left main coronary artery disease	PCI 65.2 ± 9.7 vs CABG 65.0 ± 9.8	TOTAL: 1800 (WOMEN 402, 23%) MEN 1398	12 months	Percutaneous coronary intervention (PCI) involving drug-eluting stents vs. coronary-artery bypass grafting (CABG)	Major adverse cardiac and cerebrovascular events (i.e. death from any cause, stroke, myocardial infarction, or repeat revascularization) throughout the 12-month period after randomization	TOTAL 159 (17.8) PCI vs 105 (12.4) CABG	RR = 1.44 [95% CI: 1.15 -1. 81] P = 0.002	Results by gender not reported
TIMACS (Mehta et al ¹⁰⁷)	MAY 2009	Patients with acute coronary syndromes undergoing either routine early intervention (coronary angiography ≤24 hours after randomization) or delayed intervention (coronary angiography ≥36 hours after randomization). (International with significant European component)	65.0 Early Intervention, 65.7 Delayed Intervention	TOTAL: 3031 (WOMEN: 1051, 34.6%) (MEN: 1980)	6 Months	Routine early intervention (coronary angiography ≤24 hours after randomization) versus delayed intervention (coronary angiography ≥36 hours after randomization).	Composite of death, myocardial infarction, or stroke at 6 months	Early-intervention: 9.6%; delayed intervention group: 11.3% WOMEN: Early 9.6% Delayed 12.3% MEN: Early 9.6% Delayed 10.7%	HR = 0.85 [95% CI: 0.68 - 1.06] P = 0.15 WOMEN HR = 0.77 [95% CI: 0.53–1.12] MEN HR = 0.89 [95% CI: 0.68–1.18] P for Interaction= 0.53	No benefit of early intervention in both gender

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META-ANALYSIS

TRIAL	YEAR	POPULATION	AGE	N° OF SUBJECTS	FOLLOW UP	TREATMENT	DESCRIPTION OF END-POINT	PRIMARY END-POINT	PRIMARY END-POINT HR	NOTES
		(Country)	mean ± sd, range	TOTAL (WOMEN n,%)	DURATION			TOTAL (WOMEN n,%) (MEN n,%)	(CI) P (WOMEN (MEN)	
Analysis of 9 trials on Bare--Metal stents (BMS), Sirolimus-eluting stents (SES) or Paclitaxel-eluting stents (PES) (Stone et al ¹⁰⁸)	MAR 2007	Patients with a single previously untreated native coronary-artery lesion (International with significant European component)	SES 61.9±11.1 BMS 61.9±10.7 PES 62.4±10.8 BMS 62.2±10.6	Pt from 4 Trials TOTAL: 1748 (WOMEN:497, 28.4%) (MEN: 1251) Pt from 5 Trials TOTAL: 3513 (WOMEN: 964, 27.4%) (MEN: 2549)	Up to 5 years	Pt from 4 Trials Sirolimus-eluting stents (SES) or Bare--Metal stents (BMS) Pt from 5 Trials Paclitaxel-eluting stents (PES) or bare-metal stents (BMS)	4-year rates of stent thrombosis, 4-year rates of target-lesion revascularization	4-year rates of stent thrombosis: BMS group 0.6% versus SES group 1.2% BMS group 0.9% versus PES group 1.3% 4-year rates of target-lesion revascularization BMS 23.6% SES 7.8% BMS 20.0% PES 10.1%	HR = 2.00 [95% CI: 0.68 -5.85] P = 0.20 HR = 1.44 [95% CI: 0.73-2.84] P = 0.30 HR = 0.29 [95%CI: 0.22-0.39] P<0.001 HR = 0.46 [95%CI: 0.38-0.55] P<0.001	Results by gender not reported

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SES versus BMS Analysis from 4 randomized trials (Solinas et al ¹³⁷)	NOV 2007	Patients undergoing percutaneous coronary intervention using sirolimus-eluting stents (International with significant European component)	SES WOMEN 65.7 ± 10.9 MEN 60.3 ± 10.9 BMS WOMEN 65.42 ± 10.53 MEN 60.52 ± 10.41	TOTAL: 1748 (WOMEN: 497, 28.4%) (MEN: 1251)	12 months	Sirolimus-eluting stents (SES) versus bare-metal stents (BMS)	MACE Binary restenosis at angiographic follow-up	In-segment binary restenosis rate WOMEN SES 6.3% vs. BMS 43.8% MEN SES 6.4% vs. BMS 35.6% 1-year MACE WOMEN SES 20 (8.1%) BMS 55 (22.3%) MEN SES 48 (7.7%) BMS 143 (23.1%)	P<0.0001 P<0.0001 P<0.0001 P<0.0001	Clinical outcomes were similar in both gender
Early Invasive vs. Conservative Treatment Strategies in Women and Men With Unstable Angina and Non-ST-Segment Elevation Myocardial Infarction (O'Donoghue et al ¹³⁰)	JULY 2008	Meta-analysis of 8 randomized trials to compare the effects of an invasive vs conservative strategy in women and men with NSTEMI ACS	weighted mean age: WOMEN 64.1 years MEN 61.3 years	TOTAL: 10412 (WOMEN: 3075, 30.3%) (MEN: 7075)	12 months		Death, nonfatal MI, or rehospitalization with ACS	OVERALL: CONSERVATIVE 1313/5067 (25.9%) vs. INVASIVE 1075/5083 (21.1%) WOMEN: 709/3075 (23%) CONSERVATIVE 385/1537 (25.0%) vs. INVASIVE 324/1538 (21.1%)	OR _{OVERALL} = 0.78 [95% CI: 0.61-0.98] OR_{WOMEN} = 0.81 [95% CI: 0.65 -1.01]	No gender significant interaction, overall. In women the benefit of invasive strategy is significant only in those at high risk, with positive biomarkers.

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Early Invasive vs. Conservative treatment strategies in women and men with unstable angina and non-ST-segment elevation myocardial infarction								<p>MEN: 1679/7075 (24%) CONSERVATIVE 928/3530 (26.3%) vs. INVASIVE 751/3545 (21.2%)</p> <p><i>BIOMARKER STATUS:</i> OVERALL Biomarker Positive (high risk) CONSERVATIVE 538/1903 INVASIVE 378/1942</p> <p>Biomarker Negative (low risk) CONSERVATIVE 463/1911 INVASIVE 381/1869</p> <p>WOMEN: Biomarker Positive CONSERVATIVE 156/550 INVASIVE 118/550</p>	<p>OR_{MEN} = 0.73 [95% CI: 0.55-0.98]</p> <p>P_{INTERACTION} = 0.26</p> <p>OR_{OVERALL} = 0.59 [95% CI: 0.51-0.69]</p> <p>OR_{OVERALL} = 0.79 [95% CI: 0.58-1.06]</p> <p>OR_{WOMEN} = 0.67 [95% CI: 0.50-0.88]</p>	

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Early Invasive vs. Conservative Treatment Strategies in Women and Men With Unstable Angina and Non-ST-Segment Elevation Myocardial Infarction								Biomarker Negative CONSERVATIVE 163/743 INVASIVE 152/743	OR_{WOMEN} = 0.94 [95% CI: 0.61-1.44]	
							MEN Biomarker Positive CONSERVATIVE 382/1353 INVASIVE 260/1392	OR_{MEN} = 0.56 [95% CI: 0.46-0.67]		
							Biomarker Negative CONSERVATIVE 300/1168 INVASIVE 229/1126	OR_{MEN} = 0.72 [95% CI: 0.51-1.01]		

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β blockers meta-analysis of 33 randomised controlled trials (Bangalore et al ¹⁰⁹)	DEC 2008	Patients having non-cardiac surgery (International with significant European component)	32.9 to 74.5	TOTAL: 12306	30 days	β-blocker versus control group	30-day all-cause mortality, cardiovascular mortality, non-fatal myocardial infarction, non-fatal stroke, heart failure, and myocardial ischaemia	Non-fatal myocardial infarction: control group 268/5775 β-blocker 179/6040 Myocardial ischaemia: control group 137/1384 β-blocker 74/1479 Non-fatal stroke: control group 17/5523 β-blocker 38/5710	OR = 0.65 [95% CI: 0.54–0.79] (number needed to treat [NNT] 63) OR = 0.36 [95% CI: 0.26–0.50] (NNT 16) OR = 2.16 [95% CI : 1.27–3.68] (number needed to harm [NNH] 293)	Percentage of women enrolled not reported Results by gender not reported

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Drug-Eluting Stents in Acute Myocardial Infarction (Brar et al ¹¹⁰)	MAY 2009	Patients with ST-segment elevation myocardial infarction (STEMI) Meta-Analysis of 13 randomized trials and 18 registries	Mean age 62 years	TRIALS: Total: 7352 REGISTRIES: Total: 26521 WOMEN 23%	TRIALS: Mean follow-up, 6-24 months REGISTRIES: 6-36 months	Drug Eluting Stent (DES) or Bare Metal Stent (BMS)	Death, myocardial infarction (MI), target vessel revascularization (TVR), and stent thrombosis	TRIALS: TVR DES 241/4515 BMS 326/2837 Death DES 167/4515 BMS 121/2837 MI DES 153/4515 BMS 121/2837 Stent thrombosis DES 128/4825 BMS 82/3147	TRIALS: RR = 0.44; [95%CI: 0.35 - 0.55] RR = 0.89 [95%CI: 0.70 - 1.14] RR = 0.82 [95%CI: 0.64 - 1.05] RR = 0.97 [95% CI: 0.73-1.28] REGISTRIES – 1 year: <i>TVR</i> RR = 0.54 [95%CI: 0.40 - 0.74] P<0.01 <i>MI</i> RR = 0.87 [95% CI: 0.62 - 1.23] P=0.44 <i>Death</i> RR = 0.68 [95% CI: 0.54 - 0.86] P<0.01 <i>Death -2 years</i> RR = 0.89 [95% CI: 0.64 - 1.22] P=0.45	Results by gender not reported