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Myocardial revascularization for stable angina in diabetic patients

A systematic review and meta-analysis of randomized clinical trials

2017 - 7 - 1

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0.1 Synthesis of the meta-analysis results

In all 6 randomised controlled trials (RCTs) were included. These included 1 studie of **CABG or PCI** involving 2,368 patients, 2 studies of **drug-eluting stents** involving 319 patients and 3 studies of **PCI** involving 2,392 patients. Results obtained by the meta-analysis are reported in the following tables, with the endpoints categorized according their results. Three classes are considered: endpoints for wich a benefit effect was detected, endpoints revealing a harmful effect and the other for wich no statistically significant difference was obtained (no evidence).

0.1.1 CABG or PCI

Only one trials including 2368 patients was found.
Among these comparisons, one trial are about CABG or PCI.
No trial was excluded on grounds of potentially flawed methodology or incomplete presentation of results. No ongoing trial was found.
Results obtained with CABG or PCI for all the endpoints with data in at least one trial are summarized table 1.

Table 1: *Results summary - CABG or PCI*

Benefit	Harmful	No evidence
	CABG or PCI versus medical treatment	
		→ 5-year death RR=0.98^{NS} [0.79;1.20] k=1

* $p < 0.05$; † $p < 0.01$; ¶ $p < 0.001$ RR: relative risk

H: heterogeneity with fixed effect model detected (heterogeneity test $p < 0.05$)

0.1.2 Drug-eluting stents

Reports of 2 trials (including 319 patients) were identified .
Among these comparisons, two trials are about sirolimus eluting stent.
No trial was excluded on grounds of potentially flawed methodology or incomplete presentation of results. No ongoing trial was found.
Results obtained with sirolimus eluting stent for all the endpoints with data in at least one trial are summarized table 2.

Table 2: *Results summary - Sirolimus eluting stent*

Benefit	Harmful	No evidence
	Sirolimus eluting stent versus bare-metal stent	

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Benefit	Harmful	No evidence
↓ MACE RR=0.55* [0.32;0.94] k=1 ↓ target-vessel revascularization RR=0.25† [0.10;0.61] k=1 ↓ target lesion revascularisation RR=0.20† [0.07;0.54] k=1		→ myocardial infarction (fatal and non fatal) RR=0.81^{NS} [0.40;1.65] k=1 → CABG RR=1.03^{NS} [0.02;51.15] k=1 → stent thrombosis (any, end of follow up) RR=1.03^{NS} [0.07;16.13] k=1 → acute stent thrombosis (<=24h) RR=1.03^{NS} [0.02;51.15] k=1 → sub acute stent thrombosis (1-30 days) RR=2.06^{NS} [0.07;60.37] k=1 → late stent thrombosis (31days - 1year) RR=0.51^{NS} [0.02;15.09] k=1 → all cause death RR=1.54^{NS} [0.27;8.96] k=1
Sirolimus eluting stent versus paclitaxel eluting stent		
		→ myocardial infarction (fatal and non fatal) RR=0.99^{NS} [0.06;15.54] k=1 → target lesion revascularisation RR=0.49^{NS} [0.09;2.63] k=1 → CABG RR=0.99^{NS} [0.02;49.23] k=1 → angiographic restenosis RR=0.40^{NS} [0.08;1.98] k=1 → all cause death RR=0.99^{NS} [0.06;15.54] k=1

* $p < 0.05$; † $p < 0.01$; ¶ $p < 0.001$ RR: relative risk

H: heterogeneity with fixed effect model detected (heterogeneity test $p < 0.05$)

0.1.3 PCI

Reports of 3 trials (including 2,410 patients) were identified .
Among these comparisons, two trials are about PCI with drug-eluting stents and one about stent.
No trial was excluded on grounds of potentially flawed methodology or incomplete presentation of results. One ongoing trial was identified.

PCI with drug-eluting stents

Results obtained with PCI with drug-eluting stents for all the endpoints with data in at least one trial are summarized table 3.

Table 3: *Results summary - PCI with drug-eluting stents*

Benefit	Harmful	No evidence
PCI with drug-eluting stents versus CABG		
	↑ long term cardiovascular events RR=1.39¶ [1.14;1.68] k=1 ↑ long term death RR=1.36* [1.05;1.77] k=1	→ 2 yr MACE RR=1.11^{NS} [0.87;1.42] k=1

continued...

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Benefit	Harmful	No evidence

* p <0.05; † p <0.01; ¶ p <0.001 RR: relative risk

H: heterogeneity with fixed effect model detected (heterogeneity test p <0.05)

Stent

Results obtained with stent for all the endpoints with data in at least one trial are summarized table 4.

Table 4: *Results summary - Stent*

Benefit	Harmful	No evidence
	Stent versus CABG	
	↑ 1 year revascularization RR=5.31¶ [1.99;14.16] k=1	→ 1 year event RR=1.25^{NS} [0.75;2.09] k=1

* p <0.05; † p <0.01; ¶ p <0.001 RR: relative risk

H: heterogeneity with fixed effect model detected (heterogeneity test p <0.05)

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1 Introduction

1.1 Aim of the report

This report review all the randomized clinical trials of myocardial revascularization for the treatment of stable angina in diabetic patients . The following classes of treatment are considered:

1. CABG or PCI
2. drug-eluting stents
3. PCI

1.2 Search strategy

The search aimed to identify all randomized clinical trials relating to the clinical effectiveness of myocardial revascularization for the treatment of stable angina in diabetic patients .

1.2.1 Sources searched

The following electronic databases were searched for relevant published literature for the period up to 2017 - 7 - 1:

- MEDLINE,
- EMBASE,
- Cochrane Database of Systematic Reviews (CDSR),
- Cochrane Central Register of Controlled Trials (CCTR),
- Health Technology Assessment (HTA) database,
- ISI Web of Science Proceedings (Index to Scientific and Technical Proceedings),
- ISI Web of Science Science Citation Index Expanded,

Each database was searched as far back as possible, with no language restrictions.
Search strategies of relevant clinical keywords were developed through reference to published strategies, and by iterative searching, whereby keywords identified in references retrieved by initial scoping searches were used to extend the search strategy and so increase the sensitivity of retrieval.
In addition, the reference lists of relevant articles were handsearched.
Attempts to identify further studies were made by consulting health technology assessment and guideline producing agencies, and research and trials registers via the Internet.
Titles and, when available, abstracts of all studies identified in the searches were assessed by a single researcher for relevance to the review. In cases of doubt, the full article was obtained.

1.2.2 Search restrictions

No language, study/publication or date restrictions were applied to the main searches.

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1.3 Inclusion criteria

Participants only those studies were included in which the participants had been diagnosed as having established stable angina.

Interventions studies in which myocardial revascularization was used.
Studies using other interventions in addition to myocardial revascularization therapy were included only if the treatment received by the intervention and control groups was identical in all respects other than the use of myocardial revascularization.

Methodology randomised controlled trials (RCTs). Trials were accepted as RCTs if the allocation of subjects to treatment groups was described by the authors as either randomised or double-blind.

1.4 Exclusion criteria

Studies considered methodologically unsound. The list of excluded studies with reason of their exclusion are given in a separate section for each treatment categories considered.

1.5 Meta-analysis strategy

Studies that met the reviews entry criteria were eligible for inclusion in the meta-analyses provided that they reported outcomes in terms of the number of subjects suffering clinical outcomes, as only this would allow calculation of the relative risk of subjects in the intervention group developing each outcome, compared with subjects in the control group.
Studies that only presented results in the form of relative risks, relative hazards or odds ratios, without the underlying numbers were also include in the meta-analyses.
Binary outcomes were analysed using the fixed-effect model. For continuous outcomes, weighted mean differences (WMDs) were analysed, using a fixed-effect model.
Heterogeneity was tested by the chi-2 test and the I2 statistic was obtained to describe the proportion of the variability.
Where quantitative heterogeneity was indicated, analysis using a random-effects model was conducted for comparison with results of fixed effect-based analysis. Results of the meta-analysis should be considered as being based on fixed-effect model unless stated otherwise.
Meta-analyses were conducted for data on 5-year death, .

1.6 Structure of the report

Each of the eligible studies is summarised in part **??**. A summary of the studies together with an evaluation of their quality is given in part I to **??**, listed by therapeutic class. The therapeutic classes included CABG or PCI, drug-eluting stents, PCI,
In these sections, studies in which an active intervention was compared with placebo or no treatment are discussed first, by intervention, followed by a discussion of those studies in which two or more active interventions were compared.

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Part I

CABG or PCI

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2 Overview of CABG or PCI

2.1 Included trials

Only one trial which randomized 2368 patients was identified. In all, 1 randomized comparison concerned CABG or PCI.
The detailed descriptions of trials and meta-analysis results is given in section 3 (page 18) for CABG or PCI.

This trial included 2368 patients and was published in 2009.
This trial was open-label in design.
It was reported in English language.
The table 2.1 (page 16) summmarizes the main characteristics of all the included trials. More detailed description is given in the following section.

2.2 Summary of meta-analysis results

The meta-analysis of the available trials about CABG or PCI provide the results listed in tables 2.2 to 2.2 (page 17) and in the following graphs.

2.2.1 CABG or PCI

No significant difference was found between **CABG or PCI** and **medical treatment** in terms of 5-year death (RR=0.98, 95% CI 0.79 to 1.20, p=0.8153, 1 trial).

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Table 2.1: *Main study characteristics - CABG or PCI*

Trial	Patients	Treatments	Trial design and method
CABG or PCI			
CABG or PCI versus medical treatment			
BARI 2D, 2009 [1, 2, 3, 4] n = 1176 vs. 1192	patients with type 2 diabetes and heart disease	prompt revascularization with intensive medical therapy **versus** intensivemedical therapy alone	open parallel groups Primary endpoint: death 49 centres, US, Canada, Brazil, Mexico, Czech Republic, Austria

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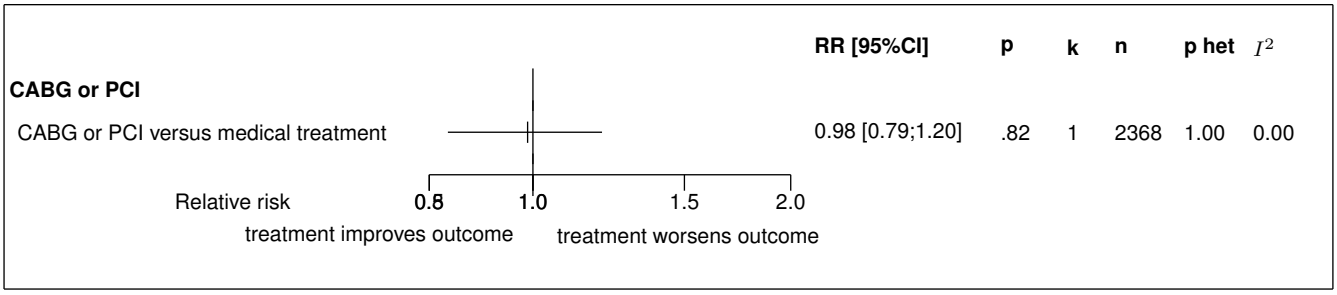
Table 2.2: *Summary of all results for CABG or PCI*

Endpoint	Effect	95% CI	p ass	p het (I^2)	k	n
CABG or PCI versus medical treatment						
5-year death	RR=0.98	0.79;1.20	0.8153	1.0000 (0.00)	1	2368

CI: confidence interval; p ass: p-value of association test; p het: p-value of the heterogeneity test; k: number of trials; n: total number of patients

Figure 2.1: *Forest's plot for 5-year death*



Results obtained with a fixed effect model except in case of heterogenity where a random model was used
RR: relative risk; 95% CI: 95% confidence interval; p: p-value of the association test; k: number of trials; n: total number of patients involving in the pooled trials; p het: p-value of the hetereogenity test; ʳ: random effect model used

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3 Details

3.1 Available trials

Only one trial which randomized 2368 patients was identified: it compared CABG or PCI with medical treatment.
This trial included 2368 patients and was published in 2009.
This trial was open-label in design.
It was reported in English language.
5-year death data was reported in 1 trials;
Following tables 3.1 (page 18), 3.2 (page 18), 3.4 (page 20), and 3.3 (page 18) summarized the main characteristics of the trial including in this systematic review of randomized trials of CABG or PCI.

Table 3.1: *Treatment description - CABG or PCI - CABG or PCI*

Trial	Studied treatment	Control treatment
CABG or PCI versus medical treatment		
BARI 2D (2009) [1, 2, 3, 4] [a]	prompt revascularization with intensive medical therapy	intensivemedical therapy alone
	Concomittant treatment: with either insulin-sensitization or insulin-provisiontherapy (factorial design)	

a) factorial design with 2nd comparison: insulin-sensitization or insulin-provisiontherapy

Table 3.2: *Descriptions of participants - CABG or PCI - CABG or PCI*

Trial	Patients
CABG or PCI versus medical treatment	
BARI 2D (2009) [1, 2, 3, 4]	Patients with type 2 diabetes and heart disease

Table 3.3: *Design and methodological quality of trials - CABG or PCI - CABG or PCI*

Trial	Design	Duration	Centre	Primary end-point
CABG or PCI versus medical treatment				
BARI 2D, 2009 [1, 2, 3, 4] n=2368	Parallel groups open confirmatory trial at risk of bias	5.3 y inclusion period: jan 2001 - mar 2005	US, Canada, Brazil, Mexico, Czech Republic, Austria 49 centres	death

continued...

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Trial	Design	Duration	Centre	Primary endpoint

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Table 3.4: *Trial characteristics - CABG or PCI - CABG or PCI*

Trial
CABG or PCI versus medical treatment
BARI 2D, 2009 [1, 2, 3, 4]

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3.2 Meta-analysis results

The results are detailed in table 3.5 (page 21). This table is followed by the Forest's plot corresponding to each endpoint.

CABG or PCI versus medical treatment

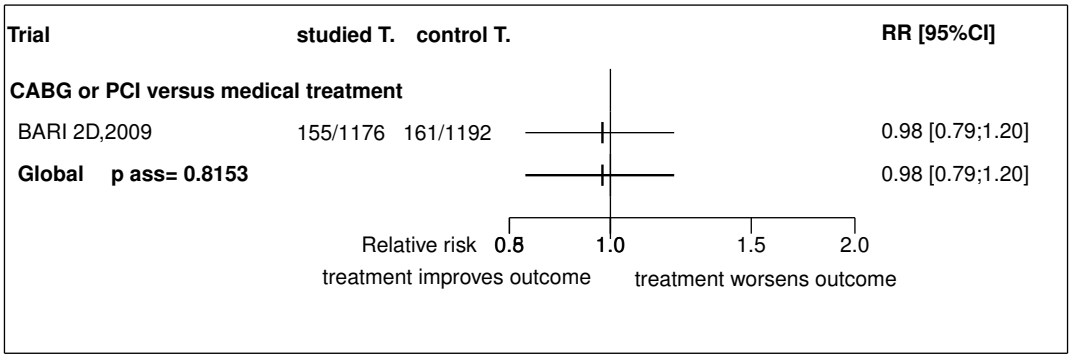
The single study eligible for this comparison provided data on **5-year death**. No statistically significant difference between the groups was found in 5-year death, with a RR of 0.98 (95% CI 0.79 to 1.20, p=0.8153).

Table 3.5: *Results details - CABG or PCI - CABG or PCI*

Comparison Endpoint	Effect	95% CI	p ass	p het	k	n
CABG or PCI versus medical treatment						
5-year death	RR=0.98	[0.79;1.20]	0.8153	1.0000 (I^2=0.00)	1	2368

CI: confidence interval; p ass: p-value of association test; p het: p-value of the heterogeneity test; k: number of trials; n: total number of patients; ES: effect size; I^2: inconsistance degree

Figure 3.1: *Forest's plot for 5-year death*



References

[1] . Baseline characteristics of patients with diabetes and coronary artery disease enrolled in the Bypass Angioplasty Revascularization Investigation 2 Diabetes (BARI 2D) trial. Am Heart J 2008;156:528-536, 536.e1-5. [PMID=18760137]

[2] . A Randomized Trial of Therapies for Type 2 Diabetes and Coronary Artery Disease. N Engl J Med 2009;:. [PMID=19502645]

[3] Chaitman BR, Hardison RM, Adler D, Gebhart S, Grogan M, Ocampo S, Sopko G, Ramires JA, Schneider D, Frye RL. The Bypass Angioplasty Revascularization Investigation 2 Diabetes Randomized Trial of Different

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Treatment Strategies in Type 2 Diabetes Mellitus With Stable Ischemic Heart Disease. Impact of Treatment Strategy on Cardiac Mortality and Myocardial Infarction. Circulation 2009;:. [PMID=19920001]

[4] Dagenais GR, Lu J, Faxon DP, Kent K, Lago RM, Lezama C, Hueb W, Weiss M, Slater J, Frye RL. Effects of Optimal Medical Treatment With or Without Coronary Revascularization on Angina and Subsequent Revascularizations in Patients With Type 2 Diabetes Mellitus and Stable Ischemic Heart Disease. Circulation 2011;123:1492-1500. [PMID=21444887]

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3.3 Individual trial summaries

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Table 3.6: *BARI 2D, 2009 - Trial synopsis*

Trial details	Patients	Treatments	Outcomes
n=2368 (1176 vs. 1192) **Follow-up duration:** 5.3 y **Study design:** Randomized controlled trial Parallel groups Open Confirmatory trial at risk of bias US, Canada, Brazil, Mexico, Czech Republic, Austria, 49 centres **Inclusion period:** jan 2001 - mar 2005	Patients with type 2 diabetes and heart disease	**Studied treatment:** prompt revascularization with intensive medical therapy **Control treatment:** intensivemedical therapy alone **Concomittant treat.:**with either insulin-sensitization or insulin-provisiontherapy (factorial design) **note:** factorial design with 2nd comparison: insulin-sensitization or insulin-provisiontherapy	5-year death RR=0.98 [0.79;1.20] (end of trial)

References

. Baseline characteristics of patients with diabetes and coronary artery disease enrolled in the Bypass Angioplasty Revascularization Investigation 2 Diabetes (BARI 2D) trial. Am Heart J 2008;156:528-536, 536.e1-5 [PMID=18760137]

. A Randomized Trial of Therapies for Type 2 Diabetes and Coronary Artery Disease. N Engl J Med 2009;: [PMID=19502645]

Chaitman BR, Hardison RM, Adler D, Gebhart S, Grogan M, Ocampo S, Sopko G, Ramires JA, Schneider D, Frye RL. The Bypass Angioplasty Revascularization Investigation 2 Diabetes Randomized Trial of Different Treatment Strategies in Type 2 Diabetes Mellitus With Stable Ischemic Heart Disease. Impact of Treatment Strategy on Cardiac Mortality and Myocardial Infarction. Circulation 2009;: [PMID=19920001]

Dagenais GR, Lu J, Faxon DP, Kent K, Lago RM, Lezama C, Hueb W, Weiss M, Slater J, Frye RL. Effects of Optimal Medical Treatment With or Without Coronary Revascularization on Angina and Subsequent Revascularizations in Patients With Type 2 Diabetes Mellitus and Stable Ischemic Heart Disease. Circulation 2011;123:1492-1500 [PMID=21444887]

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4 Global meta-analysis: all CABG or PCI

4.1 Global meta-analysis: all CABG or PCI versus medical treatment

Table 4.1: *All CABG or PCIversus medical treatment*

Endpoint	Effect	95% CI	p ass	p het (I^2)	k	n
5-year death	RR=0.98	0.79;1.20	0.8153	1.0000 (0.00)	1	2368

CI: confidence interval; p ass: p-value of association test; p het: p-value of the heterogeneity test; k: number of trials; n: total number of patients; ES: effect size; I^2: inconsistance degree

5 Ongoing studies of CABG or PCI

No ongoing trial was identified.

6 Excluded studies for CABG or PCI

No trial was excluded.

References

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Part II

Drug-eluting stents

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7 Overview of drug-eluting stents

7.1 Included trials

A total of 2 randomized comparisons which enrolled 319 patients were identified. In all, 2 randomized comparisons concerned sirolimus eluting stent.
The detailed descriptions of trials and meta-analysis results is given in section 8 (page 36) for sirolimus eluting stent.

The average study size was 159 patients (range 150 to 169). The first study was published in 2008, and the last study was published in 2008.
This trial was open-label in design.
All included studies were reported in English language. We did not found any unpublished trial.
The table 7.1 (page 30) summmarizes the main characteristics of all the included trials. More detailed description is given in the following section.

7.2 Summary of meta-analysis results

The meta-analysis of the available trials about drug-eluting stents provide the results listed in tables 7.2 to 7.2 (page 31) and in the following graphs.

7.2.1 Sirolimus eluting stent

Sirolimus eluting stent was superior to **bare-metal stent** in terms of MACE (RR=0.55, 95% CI 0.32 to 0.94, p=0.0280, 1 trial), target-vessel revascularization (RR=0.25, 95% CI 0.10 to 0.61, p=0.0026, 1 trial)and target lesion revascularisation (RR=0.20, 95% CI 0.07 to 0.54, p=0.0017, 1 trial). However, no significant difference was found on myocardial infarction (fatal and non fatal) (RR=0.81, 95% CI 0.40 to 1.65, p=0.5612, 1 trial), CABG (RR=1.03, 95% CI 0.02 to 51.15, p=0.9884, 1 trial)and all cause death (RR=1.54, 95% CI 0.27 to 8.96, p=0.6281, 1 trial).

No significant difference was found between **sirolimus eluting stent** and **paclitaxel eluting stent** in terms of myocardial infarction (fatal and non fatal) (RR=0.99, 95% CI 0.06 to 15.54, p=0.9933, 1 trial), target lesion revascularisation (RR=0.49, 95% CI 0.09 to 2.63, p=0.4081, 1 trial), CABG (RR=0.99, 95% CI 0.02 to 49.23, p=0.9953, 1 trial), angiographic restenosis (RR=0.40, 95% CI 0.08 to 1.98, p=0.2591, 1 trial)and all cause death (RR=0.99, 95% CI 0.06 to 15.54, p=0.9933, 1 trial).

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Table 7.1: *Main study characteristics - drug-eluting stents*

Trial	Patients	Treatments	Trial design and method
Sirolimus eluting stent			
Sirolimus eluting stent versus bare-metal stent			
DESSERT, 2008 [1] n = 75 vs. 75	de novo lesions of diabetic patients treated with insulin and/or oral antidiabetics for >3 months	cypher andCypher Select **versus** sonic (Cordis)	single-blind parallel groups Primary endpoint: in-stent late loss multicentre, Italy QCA follow-up duration: 8 months
Sirolimus eluting stent versus paclitaxel eluting stent			
Kim, 2008 [2] n = 85 vs. 84	korean diabetic patientswith high-grade de novo coronary lesions(stenosis of >70 percent of the luminal diameter)requiring <3 stents	cypher **versus** taxus	open parallel groups Primary endpoint: late lumen loss 6 centres, Korea

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Table 7.2: *Summary of all results for sirolimus eluting stent*

Endpoint	Effect	95% CI	p ass	p het (I^2)	k	n
sirolimus eluting stent versus bare-metal stent						
myocardial infarction (fatal and non fatal)	RR=0.81	0.40;1.65	0.5612	1.0000 (0.00)	1	138
MACE	RR=0.55	0.32;0.94	0.0280	1.0000 (0.00)	1	138
target-vessel revascularization	RR=0.25	0.10;0.61	0.0026	1.0000 (0.00)	1	138
target lesion revascularisation	RR=0.20	0.07;0.54	0.0017	1.0000 (0.00)	1	138
CABG	RR=1.03	0.02;51.15	0.9884	1.0000 (0.00)	1	138
stent thrombosis (any, end of follow up)	RR=1.03	0.07;16.13	0.9835	1.0000 (0.00)	1	138
acute stent thrombosis ($<$=24h)	RR=1.03	0.02;51.15	0.9884	1.0000 (0.00)	1	138
sub acute stent thrombosis (1-30 days)	RR=2.06	0.07;60.37	0.6752	1.0000 (0.00)	1	138
late stent thrombosis (31days - 1year)	RR=0.51	0.02;15.09	0.7000	1.0000 (0.00)	1	138
all cause death	RR=1.54	0.27;8.96	0.6281	1.0000 (0.00)	1	138
sirolimus eluting stent versus paclitaxel eluting stent						
myocardial infarction (fatal and non fatal)	RR=0.99	0.06;15.54	0.9933	1.0000 (0.00)	1	169
target lesion revascularisation	RR=0.49	0.09;2.63	0.4081	1.0000 (0.00)	1	169
CABG	RR=0.99	0.02;49.23	0.9953	1.0000 (0.00)	1	169
angiographic restenosis	RR=0.40	0.08;1.98	0.2591	1.0000 (1.00)	1	169
all cause death	RR=0.99	0.06;15.54	0.9933	1.0000 (0.00)	1	169

CI: confidence interval; p ass: p-value of association test; p het: p-value of the heterogeneity test; k: number of trials; n: total number of patients

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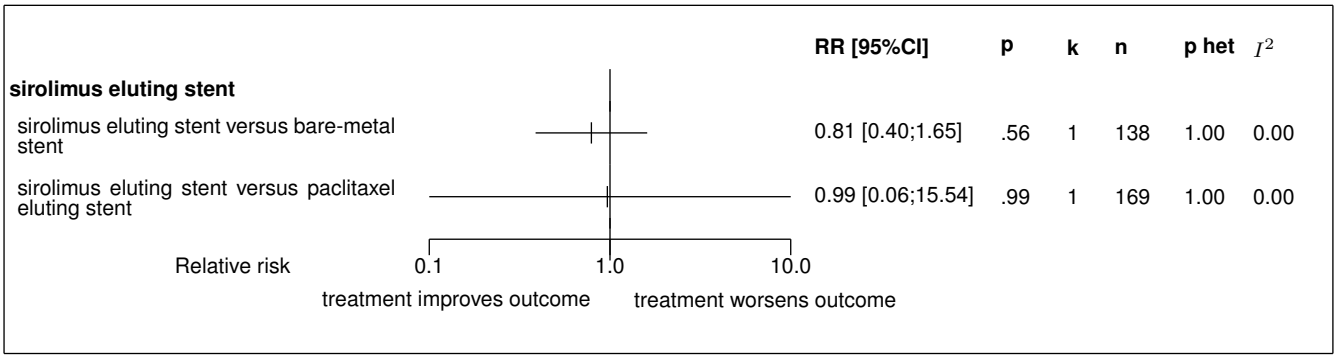
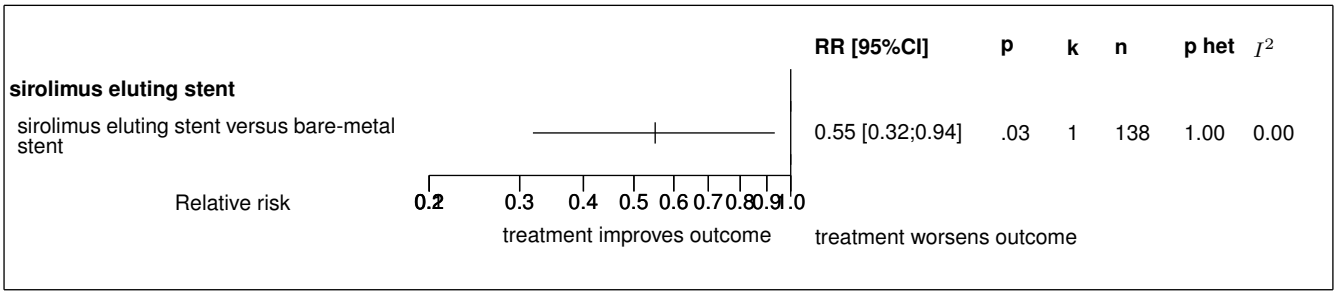
Figure 7.1: *Forest's plot for myocardial infarction (fatal and non fatal)*



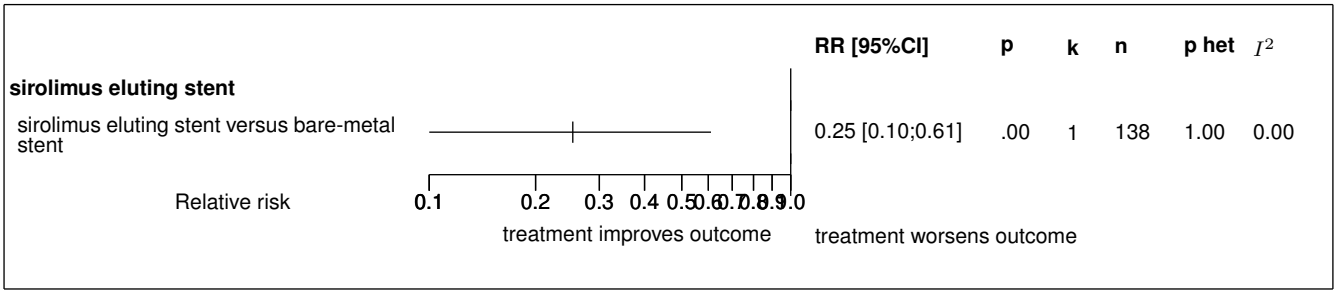
Results obtained with a fixed effect model except in case of heterogenity where a random model was used
RR: relative risk; 95% CI: 95% confidence interval; p: p-value of the association test; k: number of trials; n: total number of patients involving in the pooled trials; p het: p-value of the hetereogenity test; ᶠ: random effect model used

Figure 7.2: *Forest's plot for MACE*



Results obtained with a fixed effect model except in case of heterogenity where a random model was used
RR: relative risk; 95% CI: 95% confidence interval; p: p-value of the association test; k: number of trials; n: total number of patients involving in the pooled trials; p het: p-value of the hetereogenity test; ᶠ: random effect model used

Figure 7.3: *Forest's plot for target-vessel revascularization*



Results obtained with a fixed effect model except in case of heterogenity where a random model was used
RR: relative risk; 95% CI: 95% confidence interval; p: p-value of the association test; k: number of trials; n: total number of patients involving in the pooled trials; p het: p-value of the hetereogenity test; ᶠ: random effect model used

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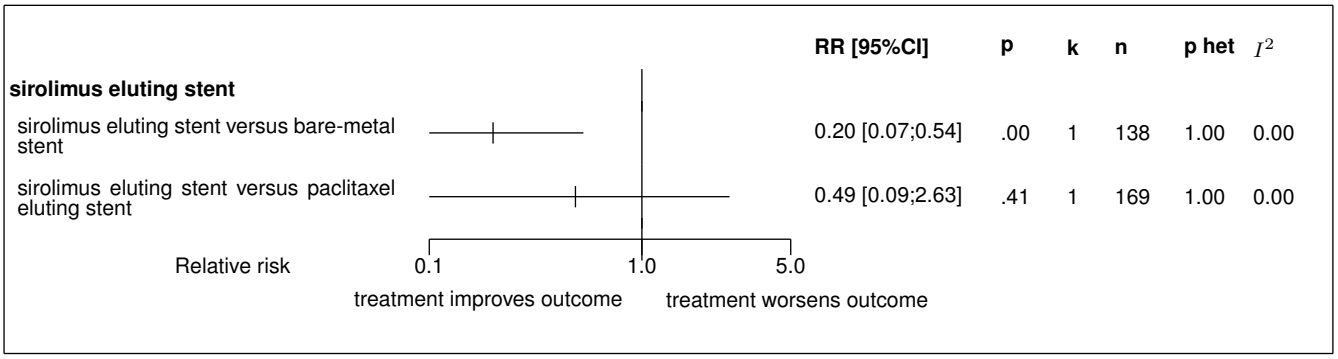
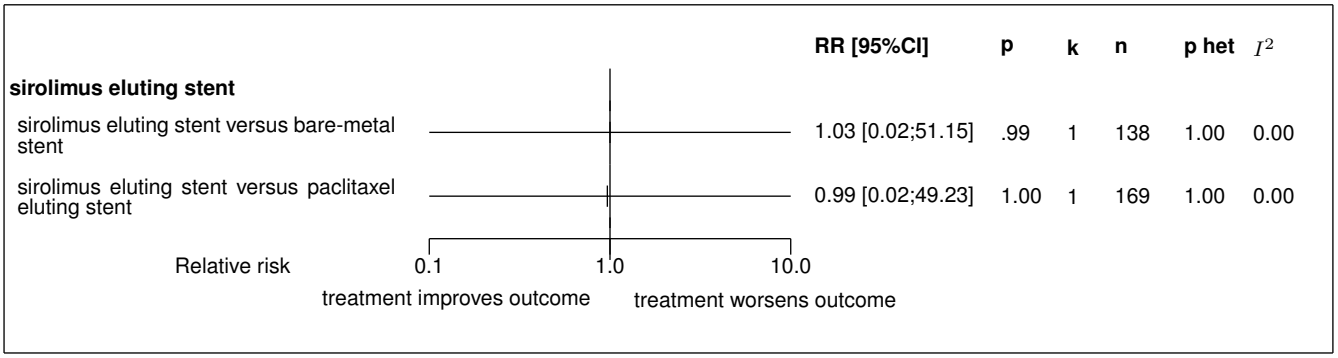
Figure 7.4: *Forest's plot for target lesion revascularisation*



Results obtained with a fixed effect model except in case of heterogenity where a random model was used
RR: relative risk; 95% CI: 95% confidence interval; p: p-value of the association test; k: number of trials; n: total number of patients involving in the pooled trials; p het: p-value of the hetereogenity test; ʳ: random effect model used

Figure 7.5: *Forest's plot for CABG*



Results obtained with a fixed effect model except in case of heterogenity where a random model was used
RR: relative risk; 95% CI: 95% confidence interval; p: p-value of the association test; k: number of trials; n: total number of patients involving in the pooled trials; p het: p-value of the hetereogenity test; ʳ: random effect model used

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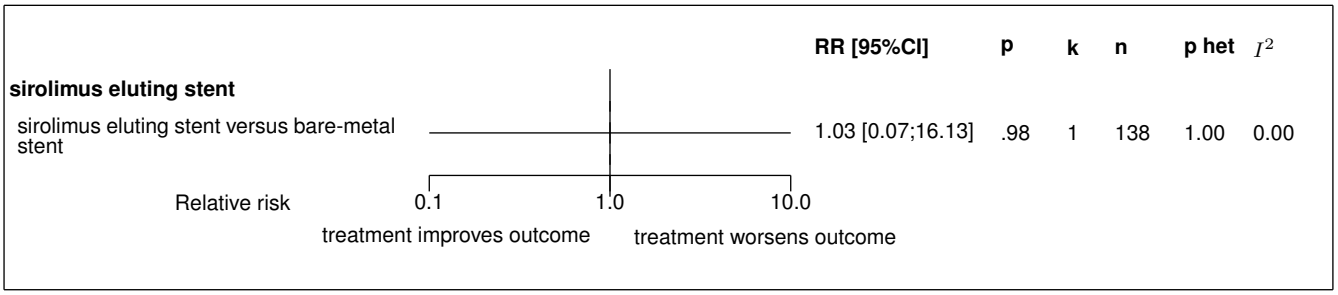
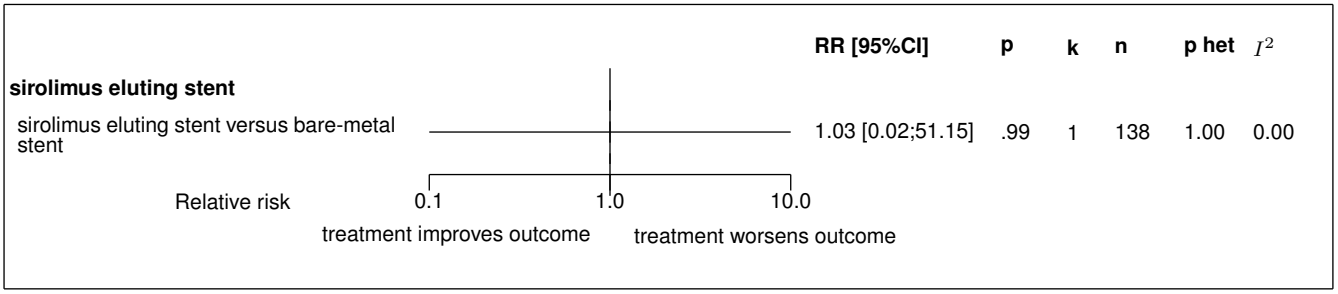
Figure 7.6: *Forest's plot for stent thrombosis (any, end of follow up)*



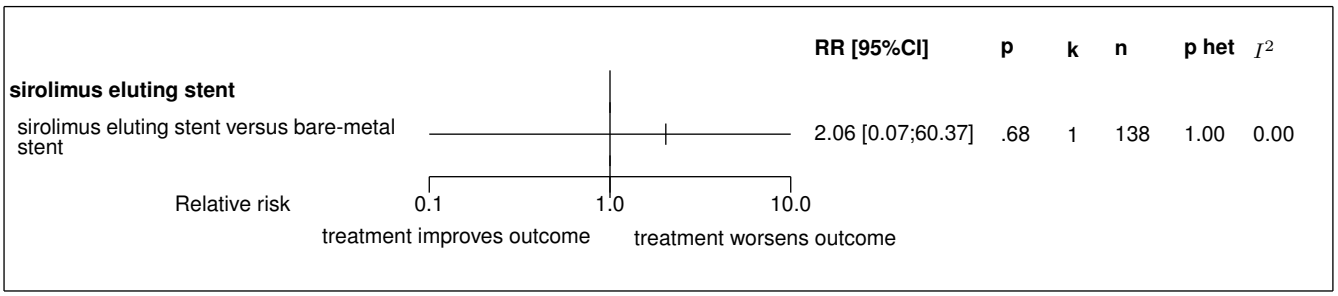
Results obtained with a fixed effect model except in case of heterogenity where a random model was used
RR: relative risk; 95% CI: 95% confidence interval; p: p-value of the association test; k: number of trials; n: total number of patients involving in the pooled trials; p het: p-value of the hetereogenity test; ʳ: random effect model used

Figure 7.7: *Forest's plot for acute stent thrombosis (<=24h)*



Results obtained with a fixed effect model except in case of heterogenity where a random model was used
RR: relative risk; 95% CI: 95% confidence interval; p: p-value of the association test; k: number of trials; n: total number of patients involving in the pooled trials; p het: p-value of the hetereogenity test; ʳ: random effect model used

Figure 7.8: *Forest's plot for sub acute stent thrombosis (1-30 days)*



Results obtained with a fixed effect model except in case of heterogenity where a random model was used
RR: relative risk; 95% CI: 95% confidence interval; p: p-value of the association test; k: number of trials; n: total number of patients involving in the pooled trials; p het: p-value of the hetereogenity test; ʳ: random effect model used

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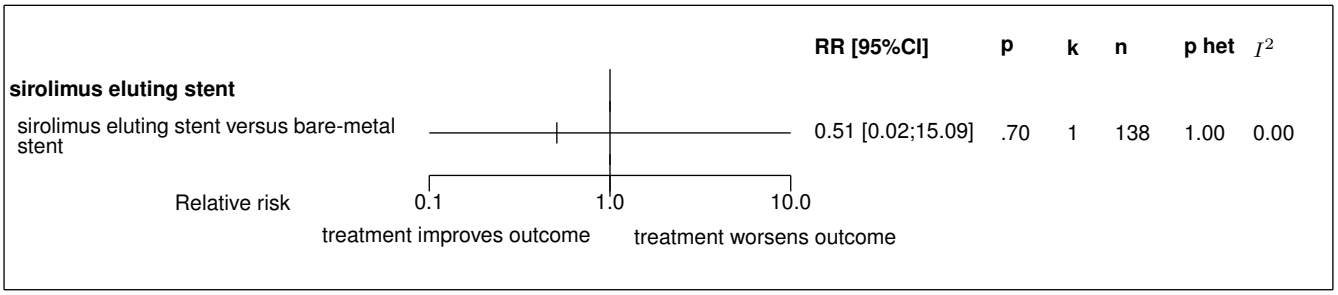
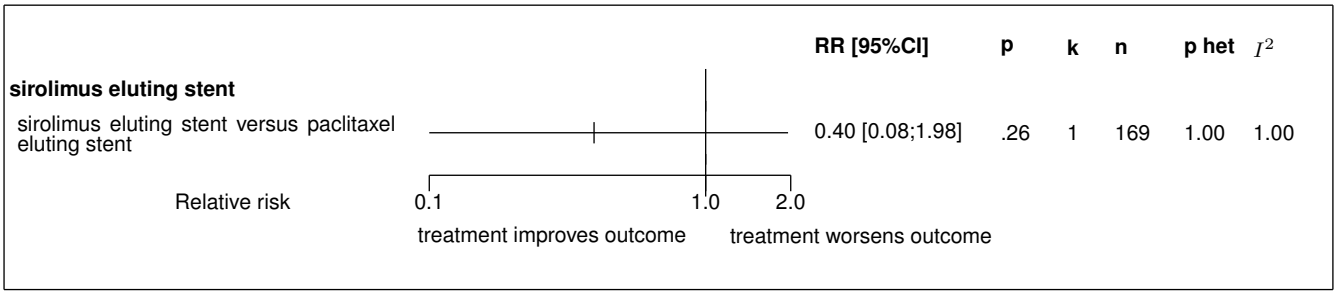
Figure 7.9: *Forest's plot for late stent thrombosis (31days - 1year)*



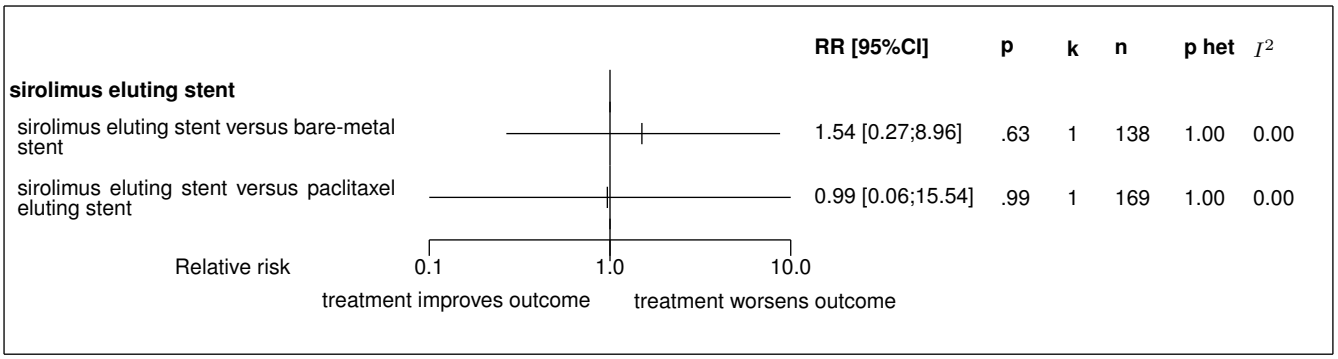
Results obtained with a fixed effect model except in case of heterogenity where a random model was used
RR: relative risk; 95% CI: 95% confidence interval; p: p-value of the association test; k: number of trials; n: total number of patients involving in the pooled trials; p het: p-value of the hetereogenity test; ʳ: random effect model used

Figure 7.10: *Forest's plot for angiographic restenosis*



Results obtained with a fixed effect model except in case of heterogenity where a random model was used
RR: relative risk; 95% CI: 95% confidence interval; p: p-value of the association test; k: number of trials; n: total number of patients involving in the pooled trials; p het: p-value of the hetereogenity test; ʳ: random effect model used

Figure 7.11: *Forest's plot for all cause death*



Results obtained with a fixed effect model except in case of heterogenity where a random model was used
RR: relative risk; 95% CI: 95% confidence interval; p: p-value of the association test; k: number of trials; n: total number of patients involving in the pooled trials; p het: p-value of the hetereogenity test; ʳ: random effect model used

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8 Details

8.1 Available trials

A total of 2 RCTs which randomized 319 patients were identified: it compared sirolimus eluting stent with bare-metal stent and it compared sirolimus eluting stent with paclitaxel eluting stent. The average study size was 159 patients (range 150 to 169). The first study was published in 2008, and the last study was published in 2008.
This trial was open-label in design.
All included studies were reported in English language. We did not found any unpublished trial. Target lesion revascularisation data was reported in 2 trials; 2 trials reported data on CABG; 2 trials reported data on all cause death; 2 trials reported data on myocardial infarction (fatal and non fatal); 1 trials reported data on angiographic restenosis; 1 trials reported data on target-vessel revascularization; 1 trials reported data on MACE; 1 trials reported data on acute stent thrombosis (<=24h); 1 trials reported data on stent thrombosis (any, end of follow up); 1 trials reported data on sub acute stent thrombosis (1-30 days); and 1 trials reported data on late stent thrombosis (31days - 1year).
Following tables 8.1 (page 36), 8.2 (page 36), 8.6 (page 40), and 8.3 (page 37) summarized the main characteristics of the trials including in this systematic review of randomized trials of sirolimus eluting stent.

Table 8.1: *Treatment description - drug-eluting stents - sirolimus eluting stent*

Trial	Studied treatment	Control treatment
Sirolimus eluting stent versus bare-metal stent		
DESSERT (2008) [1]	Cypher andCypher Select	Sonic (Cordis)
	Concomittant treatment: glycoprotein IIb/IIIainhibitors	
Sirolimus eluting stent versus paclitaxel eluting stent		
Kim (2008) [2]	Cypher	Taxus

Table 8.2: *Descriptions of participants - drug-eluting stents - sirolimus eluting stent*

Trial	Patients
Sirolimus eluting stent versus bare-metal stent	

continued...

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Trial	Patients	
DESSERT (2008) [1]	De novo lesions of diabetic patients treated with insulin and/or oral antidiabetics for >3 months	
	Inclusion criteria: diabetes mellituson insulin and/or oral hypoglycemic agent treatment for >=3 months; symptoms or objective evidence of myocardialischemia; 1 to 3 de novo significant coronarylesions in 1 or 2 coronary arteries; lesions with target-vessel diameter between 2.5 and 3.5 mm and lesionlength between13 and 25 mm	**Exclusion criteria:**
Sirolimus eluting stent versus paclitaxel eluting stent		
Kim (2008) [2]	Korean diabetic patientswith high-grade de novo coronary lesions(stenosis of >70 percent of the luminal diameter)requiring <3 stents	
	Inclusion criteria:	**Exclusion criteria:** severe uncontrolled hypertension (systolic blood pressure >180 mmHg and diastolic blood pressure >110 mmHg); acute myocardial infarction; left main coronary lesion; coronary restenosis; total occlusion of coronary artery; cerebrovascular disease;uncontrolled arrhythmia within 3 months;heart failure (ejection fraction <45% or signs of heart failure); hepatic dysfunction (serum aspartate or alanine aminotransferase levels >twice the upper limit of normal ranges); serum creatinine >2.0 mg/dL

Table 8.3: *Design and methodological quality of trials - drug-eluting stents - sirolimus eluting stent*

Trial	Design	Duration	Centre	Primary endpoint
Sirolimus eluting stent versus bare-metal stent				
DESSERT, 2008 [1] n=150	Parallel groups single-blind exploratory trial	12 months	Italy multicentre	in-stent late loss
Sirolimus eluting stent versus paclitaxel eluting stent				
Kim, 2008 [2] n=169	Parallel groups open	6 months inclusion period: Apr 2005 - Jan 2006	Korea 6 centres	late lumen loss

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Table 8.4: *Trial characteristics - drug-eluting stents - sirolimus eluting stent(continued...)*

Trial	molcule	age	Female (%)	male (%)	unstable angina (%)	history of MI (%)	diabetes (%)	Smoker (%)
Sirolimus eluting stent versus bare-metal stent								
DESSERT, 2008 [1]		70		56	47.5	30.5	100%	41
Sirolimus eluting stent versus paclitaxel eluting stent								
Kim, 2008 [2]		62.2		74	60.9	14.8	100%	23.1

continued...

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Table 8.5: *Trial characteristics - drug-eluting stents - sirolimus eluting stent(continued...)*

Trial	restenotic lesion	lesions in a bypass graft	bifurcated lesions	left main coronary artery disease	totally occluded lesions	ostial lesion	LAD (%)	RCA (%)
Sirolimus eluting stent versus bare-metal stent								
DESSERT, 2008 [1]							58.5	36
Sirolimus eluting stent versus paclitaxel eluting stent								
Kim, 2008 [2]							54.4%	37.9%

continued...

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Table 8.6: *Trial characteristics - drug-eluting stents - sirolimus eluting stent*

Trial	LCx (%)	lesion length (mm)	reference-vessel diameter	QCA follow-up duration	%QCA follow-up
Sirolimus eluting stent versus bare-metal stent					
DESSERT, 2008 [1]	25	19.85	3.0	8 months	
Sirolimus eluting stent versus paclitaxel eluting stent					
Kim, 2008 [2]	20.1%	12.9 mm	2.75 mm		

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8.2 Meta-analysis results

The results are detailed in table 8.7 (page 41). This table is followed by the Forest's plot corresponding to each endpoint.

Sirolimus eluting stent versus bare-metal stent

The single study eligible for this comparison provided data on **myocardial infarction (fatal and non fatal)**. No statistically significant difference between the groups was found in myocardial infarction (fatal and non fatal), with a RR of 0.81 (95% CI 0.40 to 1.65, p=0.5612).
The single study eligible for this comparison provided data on **MACE**. The analysis detected a statistically significant difference in favor of sirolimus eluting stent in MACE, with a RR of 0.55 (95% CI 0.32 to 0.94, p=0.0280).
The single study eligible for this comparison provided data on **target-vessel revascularization**. The analysis detected a statistically significant difference in favor of sirolimus eluting stent in target-vessel revascularization, with a RR of 0.25 (95% CI 0.10 to 0.61, p=0.0026).
The single study eligible for this comparison provided data on **target lesion revascularisation**. The analysis detected a statistically significant difference in favor of sirolimus eluting stent in target lesion revascularisation, with a RR of 0.20 (95% CI 0.07 to 0.54, p=0.0017).
The single study eligible for this comparison provided data on **CABG**. No statistically significant difference between the groups was found in CABG, with a RR of 1.03 (95% CI 0.02 to 51.15, p=0.9884).
The single study eligible for this comparison provided data on **all cause death**. No statistically significant difference between the groups was found in all cause death, with a RR of 1.54 (95% CI 0.27 to 8.96, p=0.6281).

Sirolimus eluting stent versus paclitaxel eluting stent

The single study eligible for this comparison provided data on **myocardial infarction (fatal and non fatal)**. No statistically significant difference between the groups was found in myocardial infarction (fatal and non fatal), with a RR of 0.99 (95% CI 0.06 to 15.54, p=0.9933).
The single study eligible for this comparison provided data on **target lesion revascularisation**. No statistically significant difference between the groups was found in target lesion revascularisation, with a RR of 0.49 (95% CI 0.09 to 2.63, p=0.4081).
The single study eligible for this comparison provided data on **CABG**. No statistically significant difference between the groups was found in CABG, with a RR of 0.99 (95% CI 0.02 to 49.23, p=0.9953).
The single study eligible for this comparison provided data on **angiographic restenosis**. No statistically significant difference between the groups was found in angiographic restenosis, with a RR of 0.40 (95% CI 0.08 to 1.98, p=0.2591).
The single study eligible for this comparison provided data on **all cause death**. No statistically significant difference between the groups was found in all cause death, with a RR of 0.99 (95% CI 0.06 to 15.54, p=0.9933).

Table 8.7: *Results details - drug-eluting stents - sirolimus eluting stent*

Comparison Endpoint	Effect	95% CI	p ass	p het	k	n
sirolimus eluting stent versus bare-metal stent						
myocardial infarction (fatal and non fatal)	RR=0.81	[0.40;1.65]	0.5612	1.0000 (I^2=0.00)	1	138

continued...

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Comparison Endpoint	Effect	95% CI	p ass	p het	k	n
MACE	RR=0.55	[0.32;0.94]	0.0280	1.0000 (I^2=0.00)	1	138
target-vessel revascularization	RR=0.25	[0.10;0.61]	0.0026	1.0000 (I^2=0.00)	1	138
target lesion revascularisation	RR=0.20	[0.07;0.54]	0.0017	1.0000 (I^2=0.00)	1	138
CABG	RR=1.03	[0.02;51.15]	0.9884	1.0000 (I^2=0.00)	1	138
stent thrombosis (any, end of follow up)	RR=1.03	[0.07;16.13]	0.9835	1.0000 (I^2=0.00)	1	138
acute stent thrombosis ($<$=24h)	RR=1.03	[0.02;51.15]	0.9884	1.0000 (I^2=0.00)	1	138
sub acute stent thrombosis (1-30 days)	RR=2.06	[0.07;60.37]	0.6752	1.0000 (I^2=0.00)	1	138
late stent thrombosis (31days - 1year)	RR=0.51	[0.02;15.09]	0.7000	1.0000 (I^2=0.00)	1	138
all cause death	RR=1.54	[0.27;8.96]	0.6281	1.0000 (I^2=0.00)	1	138
sirolimus eluting stent versus paclitaxel eluting stent						
myocardial infarction (fatal and non fatal)	RR=0.99	[0.06;15.54]	0.9933	1.0000 (I^2=0.00)	1	169
target lesion revascularisation	RR=0.49	[0.09;2.63]	0.4081	1.0000 (I^2=0.00)	1	169
CABG	RR=0.99	[0.02;49.23]	0.9953	1.0000 (I^2=0.00)	1	169
angiographic restenosis	RR=0.40	[0.08;1.98]	0.2591	1.0000 (I^2=1.00)	1	169
all cause death	RR=0.99	[0.06;15.54]	0.9933	1.0000 (I^2=0.00)	1	169

CI: confidence interval; p ass: p-value of association test; p het: p-value of the heterogeneity test; k: number of trials; n: total number of patients; ES: effect size; I^2: inconsistance degree

Figure 8.1: *Forest's plot for myocardial infarction (fatal and non fatal)*

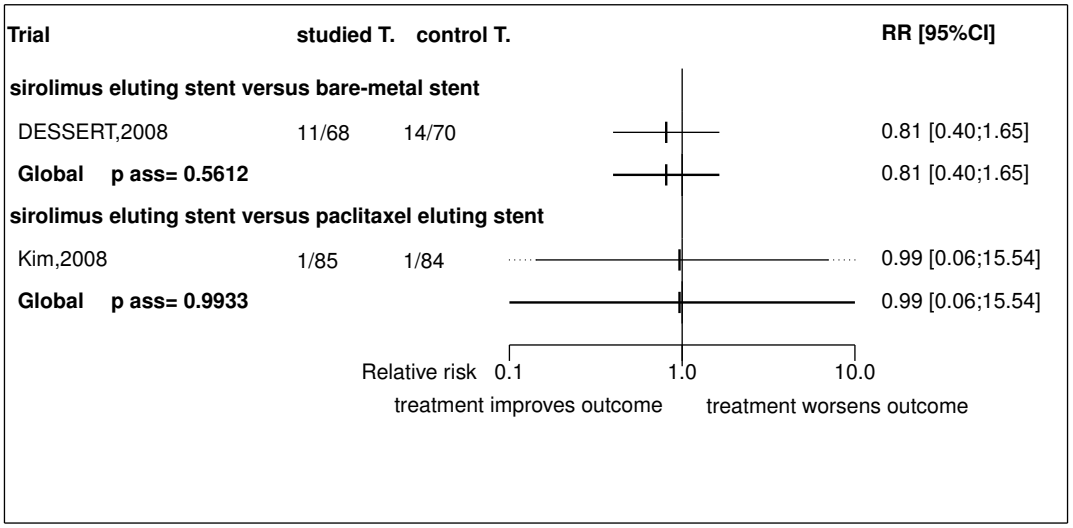

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Figure 8.2: *Forest's plot for MACE*

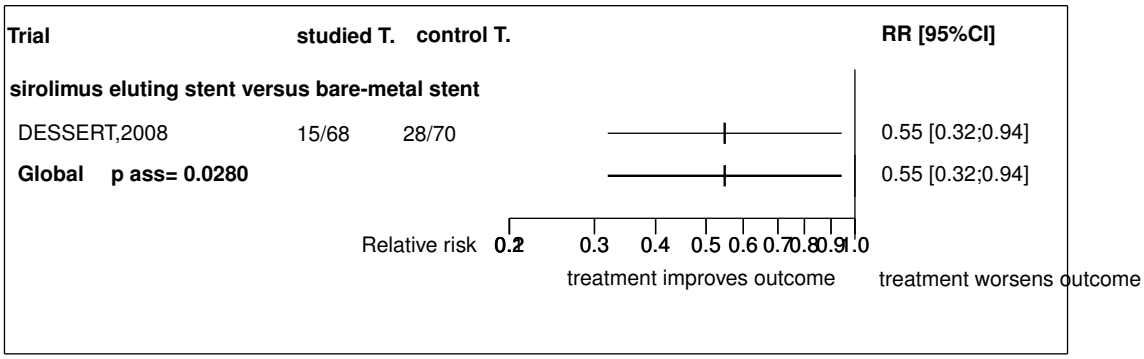

Figure 8.3: *Forest's plot for target-vessel revascularization*

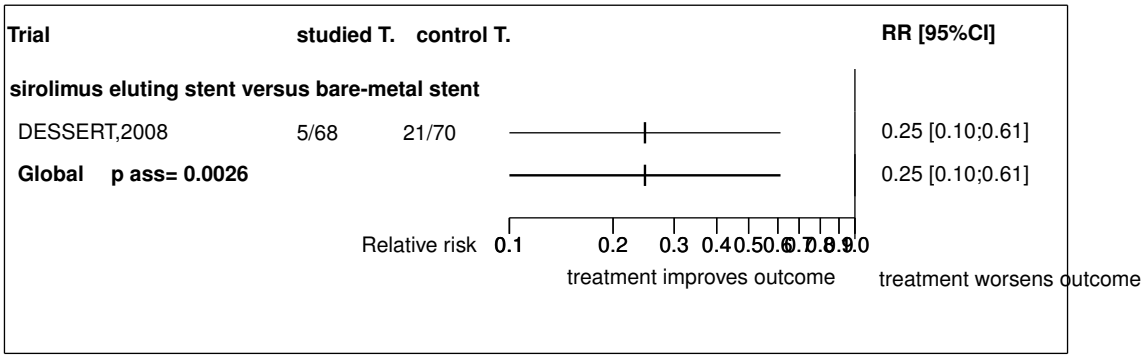

Figure 8.4: *Forest's plot for target lesion revascularisation*

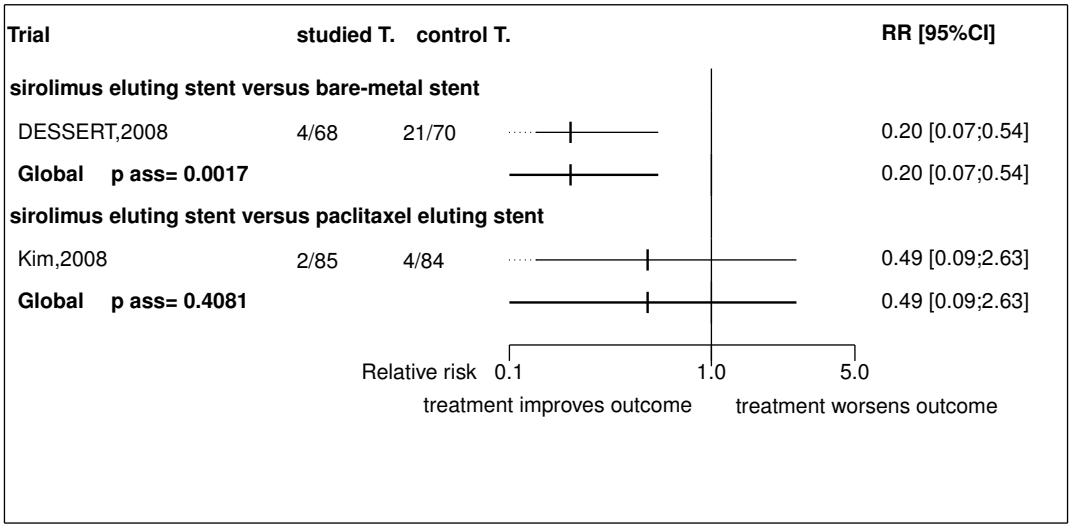

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Figure 8.5: *Forest's plot for CABG*

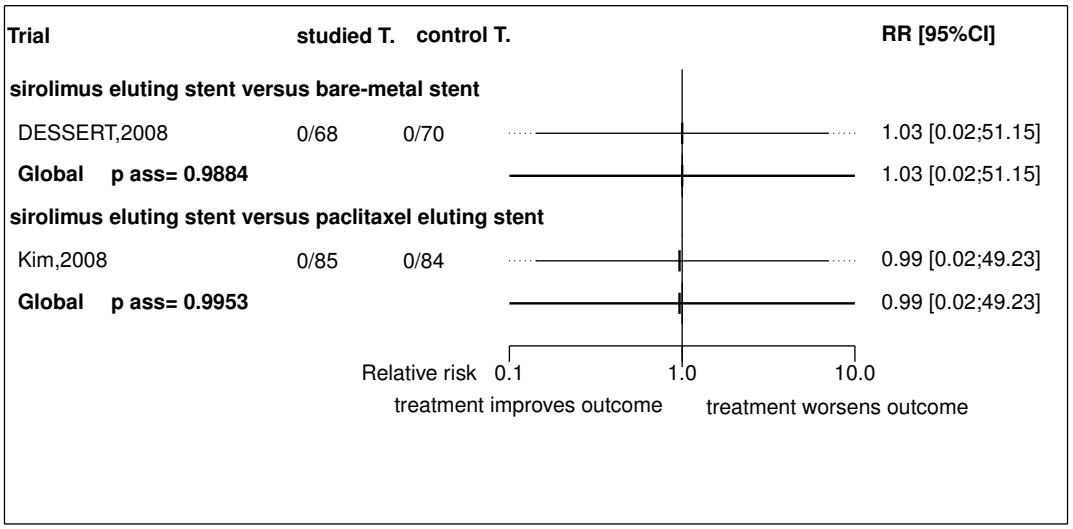

Figure 8.6: *Forest's plot for stent thrombosis (any, end of follow up)*

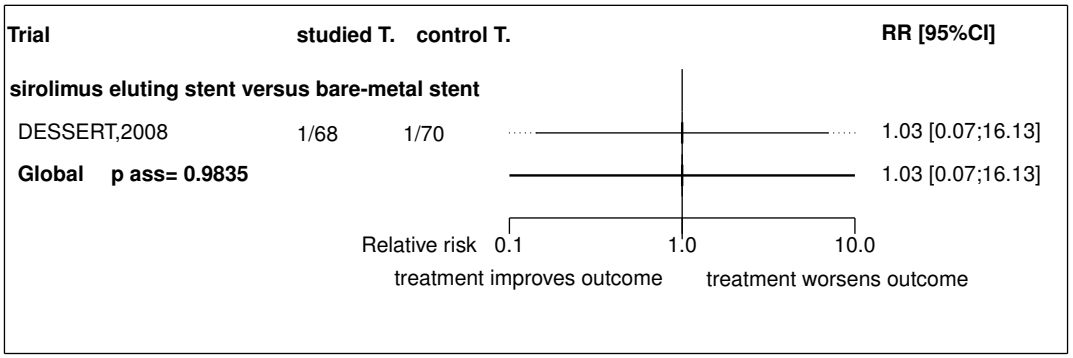

Figure 8.7: *Forest's plot for acute stent thrombosis (<=24h)*

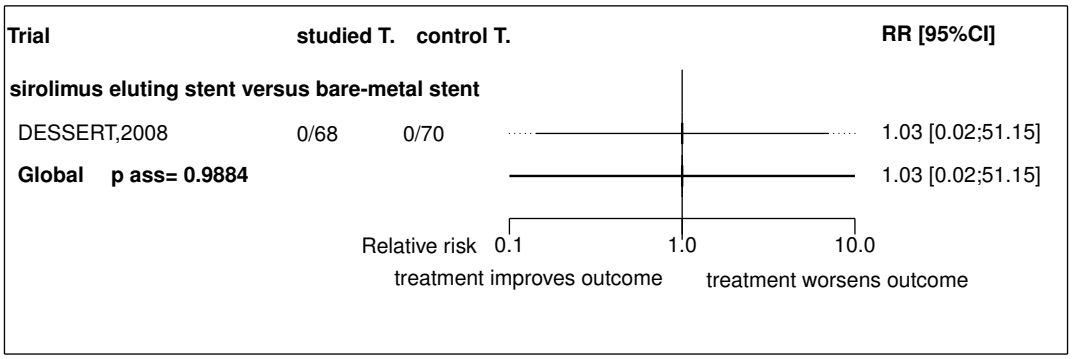

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Figure 8.8: *Forest's plot for sub acute stent thrombosis (1-30 days)*

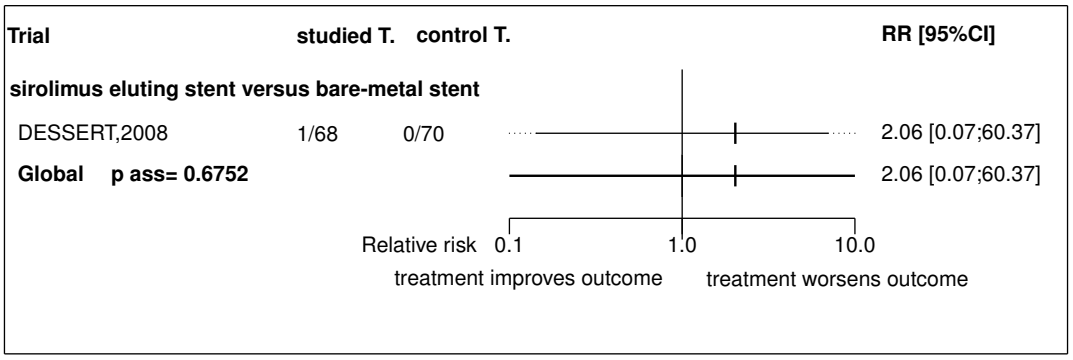

Figure 8.9: *Forest's plot for late stent thrombosis (31days - 1year)*

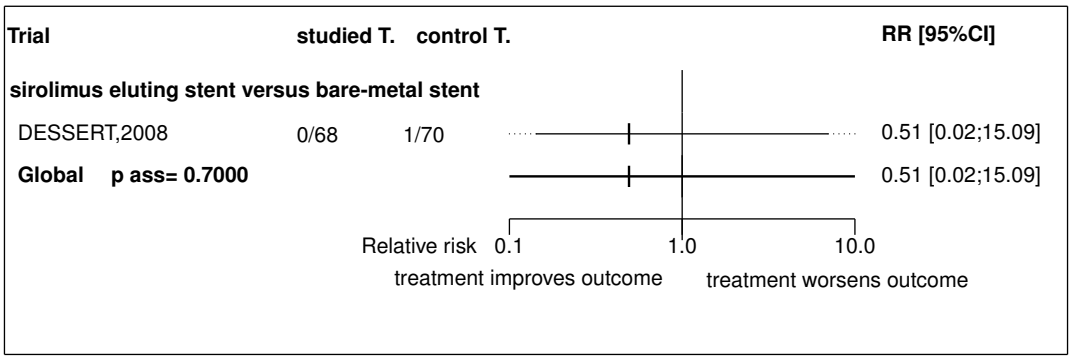

Figure 8.10: *Forest's plot for angiographic restenosis*

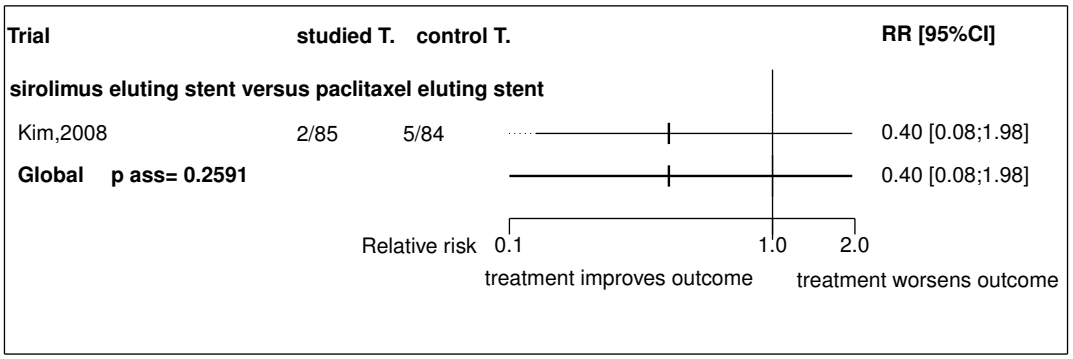

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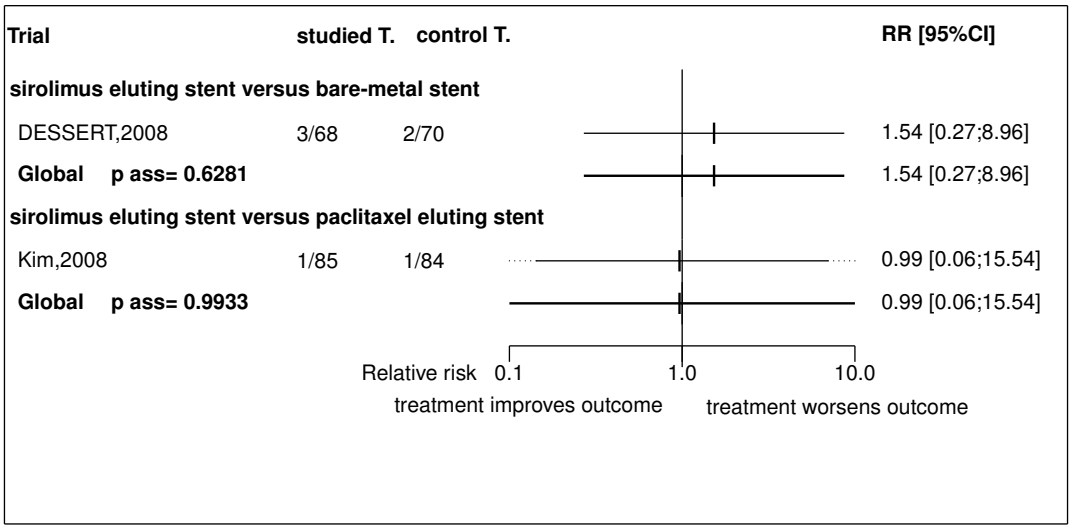
Figure 8.11: *Forest's plot for all cause death*



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[1] Maresta A, Varani E, Balducelli M, Varbella F, Lettieri C, Uguccioni L, Sangiorgio P, Zoccai GB. Comparison of effectiveness and safety of sirolimus-eluting stents versus bare-metal stents in patients with diabetes mellitus (from the Italian Multicenter Randomized DESSERT Study). Am J Cardiol 2008;101:1560-6. [PMID=18489933]

[2] Kim MH, Hong SJ, Cha KS, Park HS, Chae SC, Hur SH, Gwon HC, Bae JH, Lim DS. Effect of Paclitaxel-eluting versus sirolimus-eluting stents on coronary restenosis in Korean diabetic patients. J Interv Cardiol 2008 Jun;21:225-31. [PMID=18341520]

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8.3 Individual trial summaries

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Table 8.8: *DESSERT, 2008 - Trial synopsis*

Trial details	Patients	Treatments	Outcomes
n=150 (75 vs. 75) **Follow-up duration:** 12 months **Study design:** Randomized controlled trial Parallel groups Single-blind Exploratory trial Italy, multicentre	De novo lesions of diabetic patients treated with insulin and/or oral antidiabetics for >3 months **Inclusion criteria:** diabetes mellituson insulin and/or oral hypoglycemic agent treatment for >=3 months; symptoms or objective evidence of myocardialischemia; 1 to 3 de novo significant coronarylesions in 1 or 2 coronary arteries; lesions with target-vessel diameter between 2.5 and 3.5 mm and lesionlength between13 and 25 mm	**Studied treatment:** Cypher andCypher Select **Control treatment:** Sonic (Cordis) **Concomittant treat.:**glycoprotein IIb/IIIainhibitors	

Reference

Maresta A, Varani E, Balducelli M, Varbella F, Lettieri C, Uguccioni L, Sangiorgio P, Zoccai GB. Comparison of effectiveness and safety of sirolimus-eluting stents versus bare-metal stents in patients with diabetes mellitus (from the Italian Multicenter Randomized DESSERT Study). Am J Cardiol 2008;101:1560-6 [PMID=18489933]

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Table 8.9: *Kim, 2008 - Trial synopsis*

Trial details	Patients	Treatments	Outcomes
n=169 (85 vs. 84) **Follow-up duration:** 6 months **Study design:** Randomized controlled trial Parallel groups Open Korea, 6 centres **Inclusion period:** Apr 2005 - Jan 2006	Korean diabetic patientswith high-grade de novo coronary lesions(stenosis of >70 percent of the luminal diameter)requiring <3 stents **Exclusion criteria:** severe uncontrolled hypertension (systolic blood pressure >180 mmHg and diastolic blood pressure >110 mmHg); acute myocardial infarction; left main coronary lesion; coronary restenosis; total occlusion of coronary artery; cerebrovascular disease;uncontrolled arrhythmia within 3 months;heart failure (ejection fraction <45% or signs of heart failure); hepatic dysfunction (serum aspartate or alanine aminotransferase levels >twice the upper limit of normal ranges); serum creatinine >2.0 mg/dL	**Studied treatment:** Cypher **Control treatment:** Taxus	

Reference

Kim MH, Hong SJ, Cha KS, Park HS, Chae SC, Hur SH, Gwon HC, Bae JH, Lim DS. Effect of Paclitaxel-eluting versus sirolimus-eluting stents on coronary restenosis in Korean diabetic patients. J Interv Cardiol 2008 Jun;21:225-31 [PMID=18341520]

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9 Global meta-analysis: all drug-eluting stents

9.1 Global meta-analysis: all drug-eluting stents versus bare-metal stent

Table 9.1: *All drug-eluting stentsversus bare-metal stent*

Endpoint	Effect	95% CI	p ass	p het (I^2)	k	n
myocardial infarction (fatal and non fatal)	RR=0.81	0.40;1.65	0.5612	1.0000 (0.00)	1	138
MACE	RR=0.55	0.32;0.94	0.0280	1.0000 (0.00)	1	138
target-vessel revascularization	RR=0.25	0.10;0.61	0.0026	1.0000 (0.00)	1	138
target lesion revascularisation	RR=0.20	0.07;0.54	0.0017	1.0000 (0.00)	1	138
CABG	RR=1.03	0.02;51.15	0.9884	1.0000 (0.00)	1	138
all cause death	RR=1.54	0.27;8.96	0.6281	1.0000 (0.00)	1	138

CI: confidence interval; p ass: p-value of association test; p het: p-value of the heterogeneity test; k: number of trials; n: total number of patients; ES: effect size; I^2: inconsistance degree

9.2 Global meta-analysis: all drug-eluting stents versus paclitaxel eluting stent

Table 9.2: *All drug-eluting stentsversus paclitaxel eluting stent*

Endpoint	Effect	95% CI	p ass	p het (I^2)	k	n
myocardial infarction (fatal and non fatal)	RR=0.99	0.06;15.54	0.9933	1.0000 (0.00)	1	169
target lesion revascularisation	RR=0.49	0.09;2.63	0.4081	1.0000 (0.00)	1	169
CABG	RR=0.99	0.02;49.23	0.9953	1.0000 (0.00)	1	169
angiographic restenosis	RR=0.40	0.08;1.98	0.2591	1.0000 (1.00)	1	169
all cause death	RR=0.99	0.06;15.54	0.9933	1.0000 (0.00)	1	169

CI: confidence interval; p ass: p-value of association test; p het: p-value of the heterogeneity test; k: number of trials; n: total number of patients; ES: effect size; I^2: inconsistance degree

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10 Ongoing studies of drug-eluting stents

No ongoing trial was identified.

11 Excluded studies for drug-eluting stents

No trial was excluded.

References

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Part III

PCI

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12 Overview of PCI

12.1 Included trials

A total of 3 randomized comparisons which enrolled 2410 patients were identified. In all, 2 randomized comparisons concerned PCI with drug-eluting stents and one stent.
The detailed descriptions of trials and meta-analysis results is given in section 13 (page 60) for PCI with drug-eluting stents and in section 14 (page 70) for stent.

The average study size was 1205 patients (range 510 to 1900). The first study was published in 2008, and the last study was published in 2012.
All trials were open-label in design. All included studies were reported in English language. We did not found any unpublished trial.
The table 12.1 (page 56) summmarizes the main characteristics of all the included trials. More detailed description is given in the following section.

12.2 Summary of meta-analysis results

The meta-analysis of the available trials about PCI provide the results listed in tables 12.2 to 12.3 (page 57) and in the following graphs.

12.2.1 PCI with drug-eluting stents

PCI with drug-eluting stents was inferior to **CABG** in terms of long term cardiovascular events (RR=1.39, 95% CI 1.14 to 1.68, p=0.0000, 1 trial)and long term death (RR=1.36, 95% CI 1.05 to 1.77, p=0.0208, 1 trial). No significant difference was found on 2 yr MACE (RR=1.11, 95% CI 0.87 to 1.42, p=0.3873, 1 trial).

12.2.2 Stent

Stent was inferior to **CABG** in terms of 1 year revascularization (RR=5.31, 95% CI 1.99 to 14.16, p=0.0000, 1 trial). No significant difference was found on 1 year event (RR=1.25, 95% CI 0.75 to 2.09, p=0.3934, 1 trial).

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Table 12.1: *Main study characteristics - PCI*

Trial	Patients	Treatments	Trial design and method
PCI with drug-eluting stents			
PCI with drug-eluting stents versus CABG			
SYNTAX (diabetic), 2010 [1] n = NA vs. NA	sub group of diabetic patients with left main and/or 3-vessel disease	paclitaxel-eluting stents **versus** surgical revascularization	parallel groups
FREEDOM, 2012 [2] n = 953 vs. 947	patients with diabetes and multivessel coronary artery disease	percutaneous coronary stenting **versus** CABG	open parallel groups Primary endpoint: death, MI, stroke 140 centres, international
Stent			
Stent versus CABG			
CARDia (PCI), 2008 [1] n = 256 vs. 254	patients with diabetes and symptomatic multivessel coronary artery disease or complex single-vessel disease.	PCI plus stenting (and routine abciximab) **versus** CABG	open parallel groups Primary endpoint: death, stroke, and MI 24 centres, UK, Ireland

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Table 12.2: *Summary of all results for PCI with drug-eluting stents*

Endpoint	Effect	95% CI	p ass	p het (I^2)	k	n
PCI with drug-eluting stents versus CABG						
long term cardiovascular events	RR=1.39	1.14;1.68	0.0000	1.0000 (0.00)	1	1900
long term death	RR=1.36	1.05;1.77	0.0208	1.0000 (1.00)	1	1900
2 yr MACE	RR=1.11	0.87;1.42	0.3873	1.0000 (0.00)	1	1900

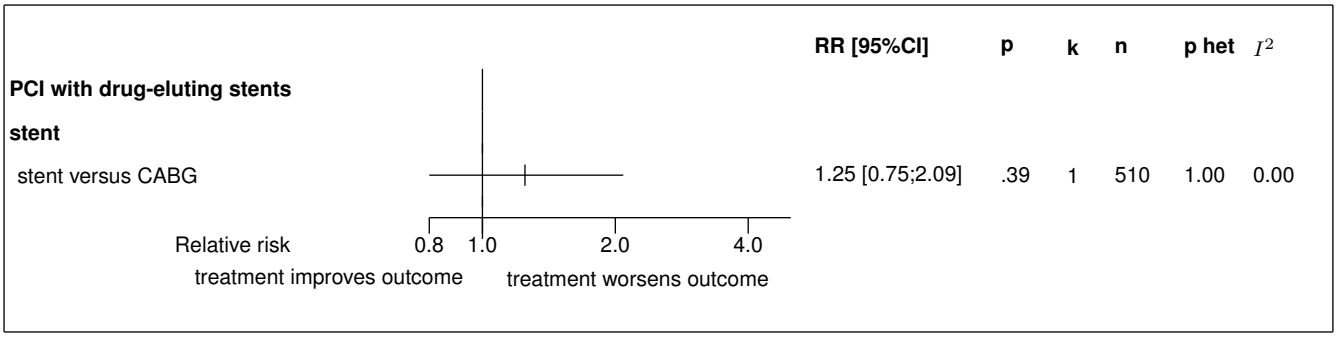
CI: confidence interval; p ass: p-value of association test; p het: p-value of the heterogeneity test; k: number of trials; n: total number of patients

Table 12.3: *Summary of all results for stent*

Endpoint	Effect	95% CI	p ass	p het (I^2)	k	n
stent versus CABG						
1 year event	RR=1.25	0.75;2.09	0.3934	1.0000 (0.00)	1	510
1 year revascularization	RR=5.31	1.99;14.16	0.0000	1.0000 (0.00)	1	510

CI: confidence interval; p ass: p-value of association test; p het: p-value of the heterogeneity test; k: number of trials; n: total number of patients

Figure 12.1: *Forest's plot for 1 year event*



Results obtained with a fixed effect model except in case of heterogenity where a random model was used
RR: relative risk; 95% CI: 95% confidence interval; p: p-value of the association test; k: number of trials; n: total number of patients involving in the pooled trials; p het: p-value of the hetereogenity test; ^{r}: random effect model used

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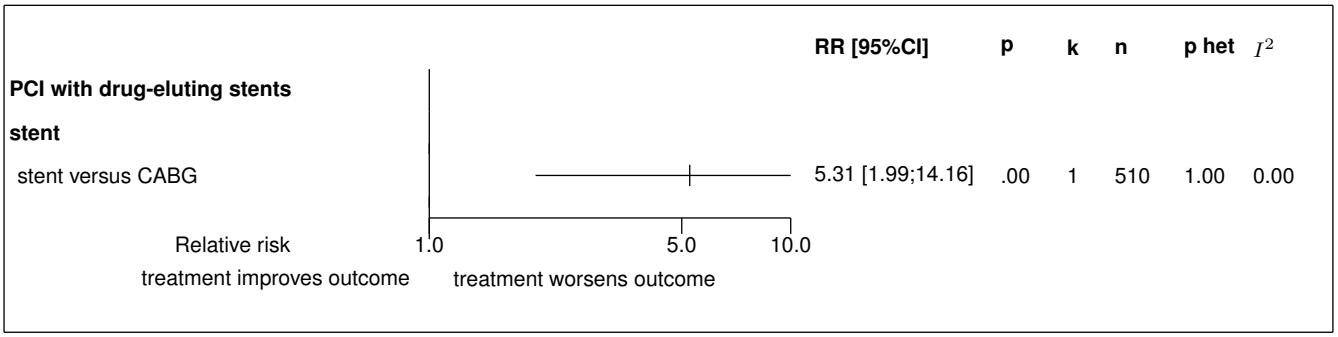
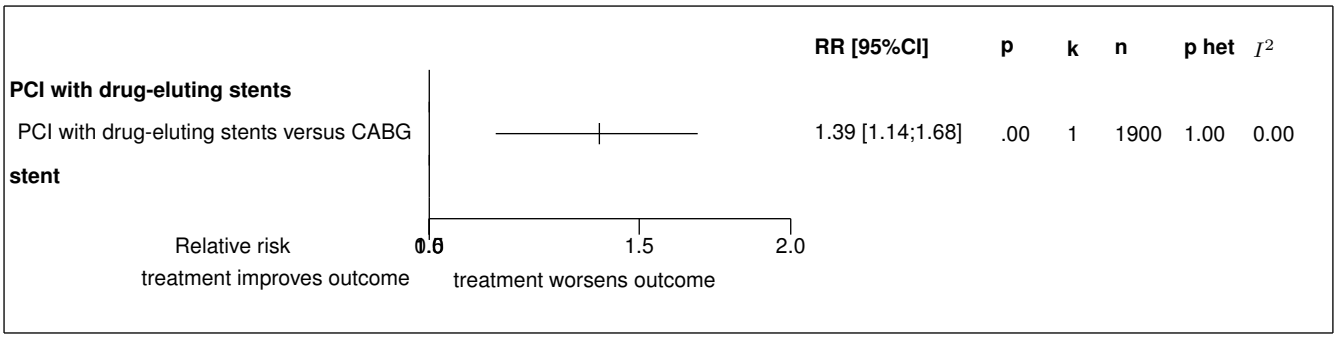
Figure 12.2: *Forest's plot for 1 year revascularization*



Results obtained with a fixed effect model except in case of heterogenity where a random model was used
RR: relative risk; 95% CI: 95% confidence interval; p: p-value of the association test; k: number of trials; n: total number of patients involving in the pooled trials; p het: p-value of the hetereogenity test; ʳ: random effect model used

Figure 12.3: *Forest's plot for long term cardiovascular events*



Results obtained with a fixed effect model except in case of heterogenity where a random model was used
RR: relative risk; 95% CI: 95% confidence interval; p: p-value of the association test; k: number of trials; n: total number of patients involving in the pooled trials; p het: p-value of the hetereogenity test; ʳ: random effect model used

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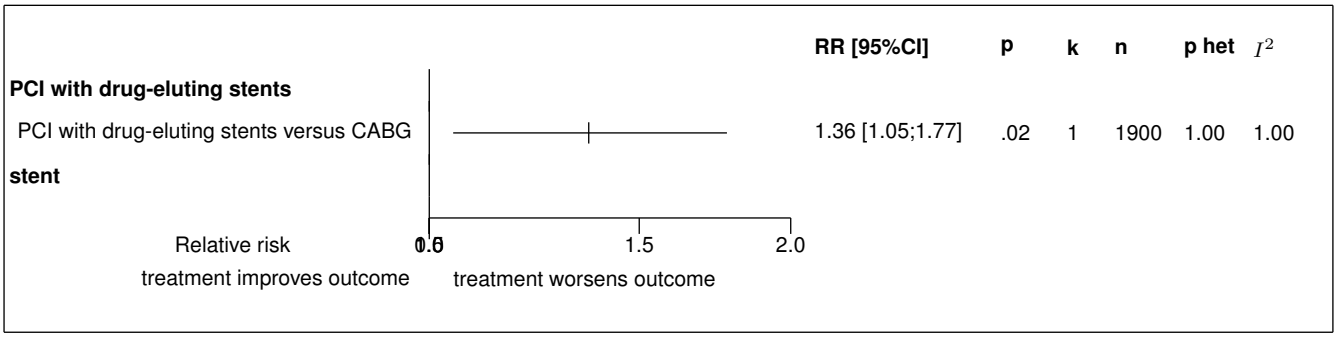
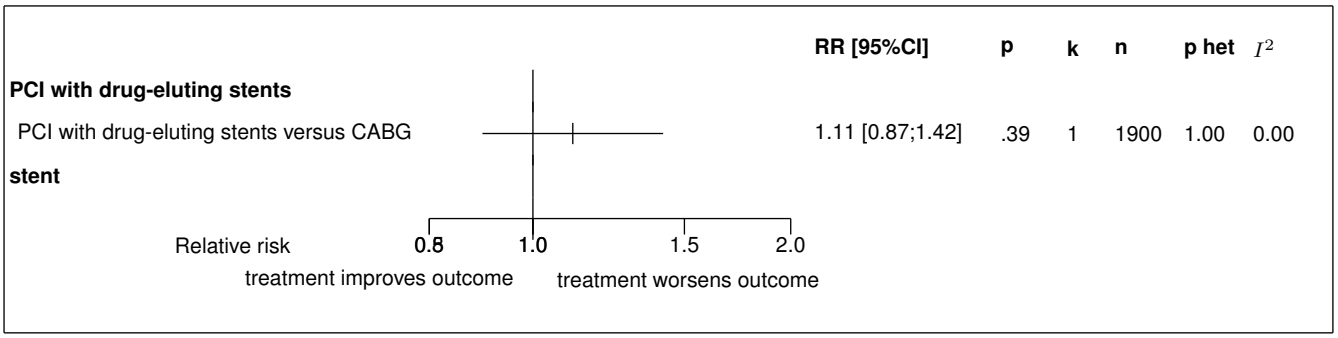
Figure 12.4: *Forest's plot for long term death*



Results obtained with a fixed effect model except in case of heterogenity where a random model was used
RR: relative risk; 95% CI: 95% confidence interval; p: p-value of the association test; k: number of trials; n: total number of patients involving in the pooled trials; p het: p-value of the hetereogenity test; ᶠ: random effect model used

Figure 12.5: *Forest's plot for 2 yr MACE*



Results obtained with a fixed effect model except in case of heterogenity where a random model was used
RR: relative risk; 95% CI: 95% confidence interval; p: p-value of the association test; k: number of trials; n: total number of patients involving in the pooled trials; p het: p-value of the hetereogenity test; ᶠ: random effect model used

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13 Detailed results for PCI with drug-eluting stents

13.1 Available trials

A total of 2 RCTs which randomized 1900 patients were identified: all compared PCI with drug-eluting stents with CABG.
The average study size was 1900 patients (range 1900 to 1900). The first study was published in 2010, and the last study was published in 2012.
This trial was open-label in design.
All included studies were reported in English language. We did not found any unpublished trial.
Long term cardiovascular events data was reported in 1 trials; 1 trials reported data on 2 yr MACE; and 1 trials reported data on long term death.
Following tables 13.1 (page 60), 13.2 (page 60), 13.4 (page 63), and 13.3 (page 61) summarized the main characteristics of the trials including in this systematic review of randomized trials of PCI with drug-eluting stents.

Table 13.1: *Treatment description - PCI - PCI with drug-eluting stents*

Trial	Studied treatment	Control treatment
PCI with drug-eluting stents versus CABG		
SYNTAX (diabetic) (2010) [1]	paclitaxel-eluting stents	surgical revascularization
FREEDOM (2012) [2]	percutaneous coronary stenting	CABG
	Concomittant treatment: recommended medical therapies for the control oflow-density lipoprotein cholesterol, systolic blood pressure, and glycated hemoglobin	

Table 13.2: *Descriptions of participants - PCI - PCI with drug-eluting stents*

Trial	Patients
PCI with drug-eluting stents versus CABG	
SYNTAX (diabetic) (2010) [1]	Sub group of diabetic patients with left main and/or 3-vessel disease

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Trial	Patients	
FREEDOM (2012) [2]	Patients with diabetes and multivessel coronary artery disease	
	Inclusion criteria: diabetes mellitus (Type 1 or Type 2) (presence of classic symptoms of diabetes mellitus with unequivocal elevation of plasma glucose 2-hour post-prandial or random of greater than 200 mg/dL (11mmol/L) or fasting plasma glucose elevation on more than one occasion of at least 126 mg/dL (7mmol/L)); Currently undergoing pharmacological or non-pharmacological treatment for diabetes; Angiographically confirmed multivessel CAD [critical (greater than or equal to 70%) lesions in at least two major epicardial vessels and in at least two separate coronary artery territories (LAD, LCX, RCA)] amenable to either PCI or CABG; Angiographic characteristics amendable to both PCI/DES and CABG; Indication for revascularization based upon symptoms of angina and/or objective evidence of myocardial ischemia	**Exclusion criteria:** severe congestive heart failure (class III or IV according to New York Heart Association [NYHA] or pulmonary edema); Prior CABG surgeryPrior valve surgery; Prior PCI with stent implantation within 6 months of study entry; stroke within 6 months of study entry; if stroke occured more than 6 months prior to study entry, must have significant residual neurologic involvement, as reflected in a Rankin Score of greater than 1Prior history of significant bleeding (within 6 months of study entry) that may occur during CABG or PCI/DES related anticoagulationIn-stent restenosis of a target vessel; Two or more chronic total occlusions in major coronary territories; Left main stenosis (at least 50% diameter stenosis); Acute ST-elevation MI (Q-wave) within 72 hours of study entry requiring revascularization; Abnormal creatine kinase level (greater than twice the normal limit); or abnormal CK-MB level at study entry; Planned simultaneous surgical procedure unrelated to coronary revascularization (e.g., valve repair/replacement, aneurysmectomy, carotid endarterectomy, or carotid stent); Cannot undergo either CABG or PCI/DES because of a coexisting medical condition; Significant leukopenia, neutropenia, thrombocytopenia, anemia, or known bleeding diathesis; Intolerance to aspirin or both clopidogrel and ticlopidine; Dementia with a score of less than 20 on the Mini Mental Status Examination (MMSE); Extra-cardiac illness that is expected to limit survival to less than 5 years (e.g., oxygen-dependent chronic obstructive pulmonary disease, active hepatitis, significant hepatic failure, or severe kidney disease)

Table 13.3: *Design and methodological quality of trials - PCI - PCI with drug-eluting stents*

Trial	Design	Duration	Centre	Primary endpoint
PCI with drug-eluting stents versus CABG				
SYNTAX (diabetic), 2010 [1] n=NaN	Parallel groups exploratory trial	1 year		
FREEDOM, 2012 [2] n=1900	Parallel groups open confirmatory trial at risk of bias	3.8 yrs (median)	international 140 centres	death, MI, stroke

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Trial	Design	Duration	Centre	Primary endpoint

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Table 13.4: *Trial characteristics - PCI - PCI with drug-eluting stents*

Trial	Age (mean, year)	Men (%)	Ejection fraction (%)	Extent of Disease	arterial grafts	stent (%)
PCI with drug-eluting stents versus CABG						
SYNTAX (diabetic), 2010 [1]						
FREEDOM, 2012 [2]						

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13.2 Meta-analysis results

The results are detailed in table 13.5 (page 64). This table is followed by the Forest's plot corresponding to each endpoint.

PCI with drug-eluting stents versus CABG

Only one of the 2 studies eligible for this comparison provided data on **long term cardiovascular events**. The analysis detected a statistically significant difference in favor of CABG in long term cardiovascular events, with a RR of 1.39 (95% CI 1.14 to 1.68, p=0.0000).
Only one of the 2 studies eligible for this comparison provided data on **long term death**. The analysis detected a statistically significant difference in favor of CABG in long term death, with a RR of 1.36 (95% CI 1.05 to 1.77, p=0.0208).
Only one of the 2 studies eligible for this comparison provided data on **2 yr MACE**. No statistically significant difference between the groups was found in 2 yr MACE, with a RR of 1.11 (95% CI 0.87 to 1.42, p=0.3873).

Table 13.5: *Results details - PCI - PCI with drug-eluting stents*

Comparison Endpoint	Effect	95% CI	p ass	p het	k	n
PCI with drug-eluting stents versus CABG						
long term cardiovascular events	RR=1.39	[1.14;1.68]	0.0000	1.0000 (I^2=0.00)	1	1900
long term death	RR=1.36	[1.05;1.77]	0.0208	1.0000 (I^2=1.00)	1	1900
2 yr MACE	RR=1.11	[0.87;1.42]	0.3873	1.0000 (I^2=0.00)	1	1900

CI: confidence interval; p ass: p-value of association test; p het: p-value of the heterogeneity test; k: number of trials; n: total number of patients; ES: effect size; I^2: inconsistance degree

Figure 13.1: *Forest's plot for long term cardiovascular events*

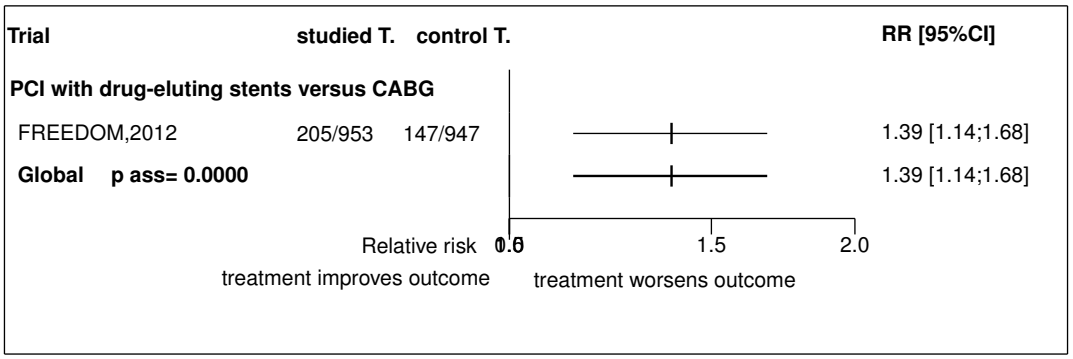

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Figure 13.2: *Forest's plot for long term death*

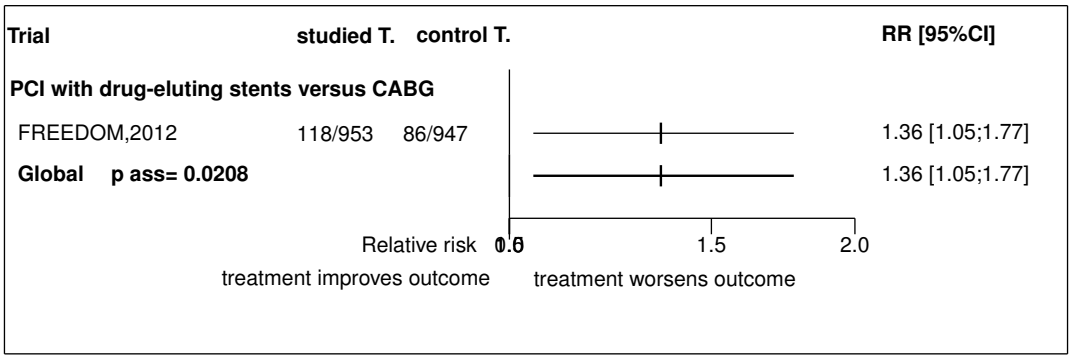
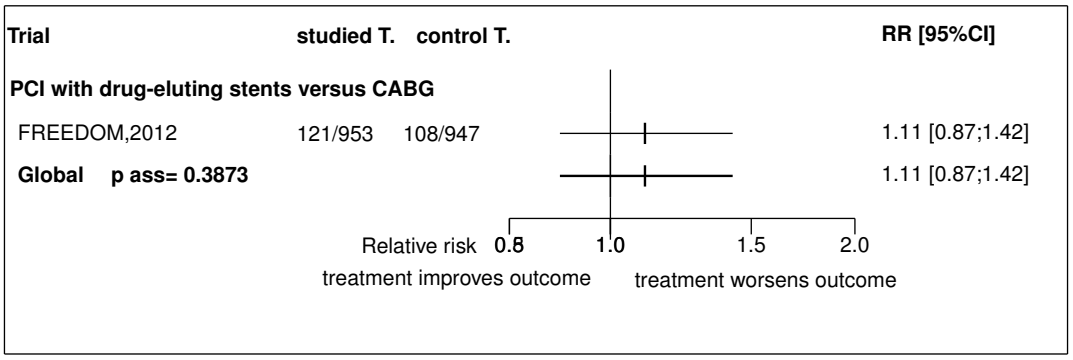


Figure 13.3: *Forest's plot for 2 yr MACE*



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[1] Banning AP, Westaby S, Morice MC, Kappetein AP, Mohr FW, Berti S, Glauber M, Kellett MA, Kramer RS, Leadley K, Dawkins KD, Serruys PW. Diabetic and nondiabetic patients with left main and/or 3-vessel coronary artery disease: comparison of outcomes with cardiac surgery and paclitaxel-eluting stents. J Am Coll Cardiol 2010;55:1067-75. [PMID=20079596]

[2] Farkouh ME, Domanski M, Sleeper LA, Siami FS, Dangas G, Mack M, Yang M, Cohen DJ, Rosenberg Y, Solomon SD, Desai AS, Gersh BJ, Magnuson EA, Lansky A, Boineau R, Weinberger J, Ramanathan K, Sousa JE, Rankin J, Bhargava B, Buse J, Hueb W, Smith CR, Muratov. Strategies for Multivessel Revascularization in Patients with Diabetes. N Engl J Med 2012 Nov 4;:. [PMID=23121323]

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13.3 Individual trial summaries

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Table 13.6: *SYNTAX (diabetic), 2010 - Trial synopsis*

Trial details	Patients	Treatments	Outcomes
n=NA (NA vs. NA) **Follow-up duration:** 1 year **Study design:** Randomized controlled trial Parallel groups Exploratory trial	Sub group of diabetic patients with left main and/or 3-vessel disease	**Studied treatment:** paclitaxel-eluting stents **Control treatment:** surgical revascularization	

Reference

Banning AP, Westaby S, Morice MC, Kappetein AP, Mohr FW, Berti S, Glauber M, Kellett MA, Kramer RS, Leadley K, Dawkins KD, Serruys PW. Diabetic and nondiabetic patients with left main and/or 3-vessel coronary artery disease: comparison of outcomes with cardiac surgery and paclitaxel-eluting stents. J Am Coll Cardiol 2010;55:1067-75 [PMID=20079596]

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Table 13.7: *FREEDOM, 2012 - Trial synopsis*

Trial details	Patients	Treatments	Outcomes
n=1900 (953 vs. 947) **Follow-up duration:** 3.8 yrs (median) **Study design:** Randomized controlled trial Parallel groups Open Confirmatory trial at risk of bias international, 140 centres	Patients with diabetes and multivessel coronary artery disease **Inclusion criteria:** Diabetes mellitus (Type 1 or Type 2) (presence of classic symptoms of diabetes mellitus with unequivocal elevation of plasma glucose 2-hour post-prandial or random of greater than 200 mg/dL (11mmol/L) or fasting plasma glucose elevation on more than one occasion of at least 126 mg/dL (7mmol/L)); Currently undergoing pharmacological or non-pharmacological treatment for diabetes; Angiographically confirmed multivessel CAD [critical (greater than or equal to 70%) lesions in at least two major epicardial vessels and in at least two separate coronary artery territories (LAD, LCX, RCA)] amenable to **Exclusion criteria:** Severe congestive heart failure (class III or IV according to New York Heart Association [NYHA] or pulmonary edema); Prior CABG surgeryPrior valve surgery; Prior PCI with stent implantation within 6 months of study entry; stroke within 6 months of study entry; if stroke occured more than 6 months prior to study entry, must have significant residual neurologic involvement, as reflected in a Rankin Score of greater than 1Prior history of significant bleeding (within 6 months of study entry) that may occur during CABG or PCI/DES related anticoagulationIn-stent restenosis of a target vessel; Two o	**Studied treatment:** percutaneous coronary stenting **Control treatment:** CABG **Concomittant treat.:**recommended medical therapies for the control oflow-density lipoprotein cholesterol, systolic blood pressure, and glycated hemoglobin	Long term cardiovascular events RR=1.39 [1.14;1.68]

continued...

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trial details	Patients	Treatments	Outcomes

Reference

Farkouh ME, Domanski M, Sleeper LA, Siami FS, Dangas G, Mack M, Yang M, Cohen DJ, Rosenberg Y, Solomon SD, Desai AS, Gersh BJ, Magnuson EA, Lansky A, Boineau R, Weinberger J, Ramanathan K, Sousa JE, Rankin J, Bhargava B, Buse J, Hueb W, Smith CR, Muratov. Strategies for Multivessel Revascularization in Patients with Diabetes. N Engl J Med 2012 Nov 4;: [PMID=23121323]

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14 Detailed results for stent

14.1 Available trials

Only one trial which randomized 510 patients was identified: it compared stent with CABG.
This trial included 510 patients and was published in 2008.
This trial was open-label in design.
It was reported in English language.
data was reported in trials;
Following tables 14.1 (page 70), 14.2 (page 70), 14.4 (page 72), and 14.3 (page 70) summarized the main characteristics of the trial including in this systematic review of randomized trials of stent.

Table 14.1: *Treatment description - PCI - stent*

Trial	Studied treatment	Control treatment
Stent versus CABG		
CARDia (PCI) (2008) [1] [a]	PCI plus stenting (and routine abciximab) bare metal stent or sirolimus-coated stents (CYPHER) and abciximab	CABG

a) BMS n=72, CYPHER n=180

Table 14.2: *Descriptions of participants - PCI - stent*

Trial	Patients	
Stent versus CABG		
CARDia (PCI) (2008) [1]	Patients with diabetes and symptomatic multivessel coronary artery disease or complex single-vessel disease.	
	Inclusion criteria: multi-vessel disease or complex single-vessel disease (ostial or proximal left anterior descending artery); diabetes mellitus; anatomy suitable for both PCI and CABG	**Exclusion criteria:** previous PCI or CABG; age >80 years; left main disease; cardiogenic shock; recent ST-elevation MI (within 6 weeks); ejection fraction <20%; contraindications to abciximab, aspirin, and clopidogrel

Table 14.3: *Design and methodological quality of trials - PCI - stent*

Trial	Design	Duration	Centre	Primary endpoint
Stent versus CABG				

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Trial	Design	Duration	Centre	Primary endpoint
CARDia (PCI), 2008 [1] n=510	Parallel groups open confirmatory trial at risk of bias	1 y	UK, Ireland 24 centres	death, stroke, and MI

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Table 14.4: *Trial characteristics - PCI - stent*

Trial	Age (mean, year)	Men (%)	Ejection fraction (%)	Extent of Disease	arterial grafts	stent (%)
Stent versus CABG						
CARDia (PCI), 2008 [1]						

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14.2 Meta-analysis results

The results are detailed in table 14.5 (page 73). This table is followed by the Forest's plot corresponding to each endpoint.

Stent versus CABG

The single study eligible for this comparison provided data on **1 year event**. No statistically significant difference between the groups was found in 1 year event, with a RR of 1.25 (95% CI 0.75 to 2.09, p=0.3934).
The single study eligible for this comparison provided data on **1 year revascularization**. The analysis detected a statistically significant difference in favor of CABG in 1 year revascularization, with a RR of 5.31 (95% CI 1.99 to 14.16, p=0.0000).

Table 14.5: *Results details - PCI - stent*

Comparison Endpoint	Effect	95% CI	p ass	p het	k	n
stent versus CABG						
1 year event	RR=1.25	[0.75;2.09]	0.3934	1.0000 (I^2=0.00)	1	510
1 year revascularization	RR=5.31	[1.99;14.16]	0.0000	1.0000 (I^2=0.00)	1	510

CI: confidence interval; p ass: p-value of association test; p het: p-value of the heterogeneity test; k: number of trials; n: total number of patients; ES: effect size; I^2: inconsistance degree

Figure 14.1: *Forest's plot for 1 year event*

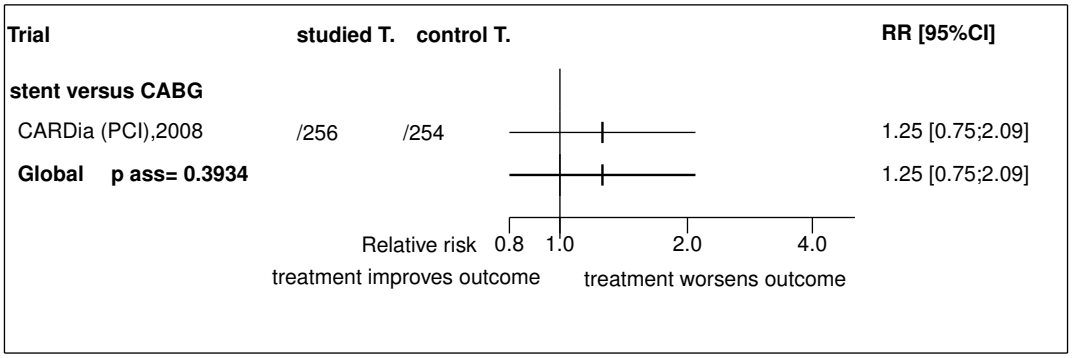

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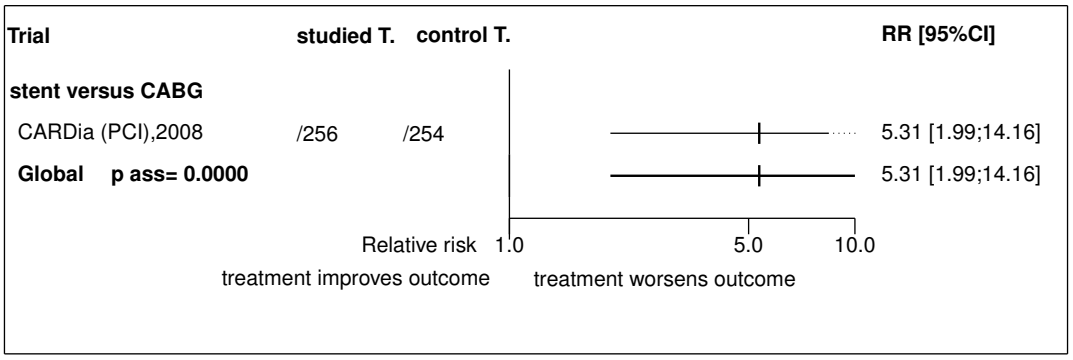
Figure 14.2: *Forest's plot for 1 year revascularization*



References

[1] Kapur A, Hall RJ, Malik IS, Qureshi AC, Butts J, de Belder M, Baumbach A, Angelini G, de Belder A, Oldroyd KG, Flather M, Roughton M, Nihoyannopoulos P, Bagger JP, Morgan K, Beatt KJ. Randomized comparison of percutaneous coronary intervention with coronary artery bypass grafting in diabetic patients. 1-year results of the CARDia (Coronary Artery Revascularization in Diabetes) trial. J Am Coll Cardiol 2010 Feb 2;55:432-40. [PMID=20117456]

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14.3 Individual trial summaries

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Table 14.6: *CARDia (PCI), 2008 - Trial synopsis*

Trial details	Patients	Treatments	Outcomes
n=510 (256 vs. 254) **Follow-up duration:** 1 y **Study design:** Randomized controlled trial Parallel groups Open Confirmatory trial at risk of bias UK, Ireland, 24 centres	Patients with diabetes and symptomatic multivessel coronary artery disease or complex single-vessel disease. **Inclusion criteria:** multi-vessel disease or complex single-vessel disease (ostial or proximal left anterior descending artery); diabetes mellitus; anatomy suitable for both PCI and CABG **Exclusion criteria:** previous PCI or CABG; age >80 years; left main disease; cardiogenic shock; recent ST-elevation MI (within 6 weeks); ejection fraction <20%; contraindications to abciximab, aspirin, and clopidogrel	**Studied treatment:** PCI plus stenting (and routine abciximab) bare metal stent or sirolimus-coated stents (CYPHER) and abciximab **Control treatment:** CABG **note:** BMS n=72, CYPHER n=180	

Reference

Kapur A, Hall RJ, Malik IS, Qureshi AC, Butts J, de Belder M, Baumbach A, Angelini G, de Belder A, Oldroyd KG, Flather M, Roughton M, Nihoyannopoulos P, Bagger JP, Morgan K, Beatt KJ. Randomized comparison of percutaneous coronary intervention with coronary artery bypass grafting in diabetic patients. 1-year results of the CARDia (Coronary Artery Revascularization in Diabetes) trial. J Am Coll Cardiol 2010 Feb 2;55:432-40 [PMID=20117456]

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15 Global meta-analysis: all PCI

15.1 Global meta-analysis: all PCI versus CABG

Table 15.1: *All PCIversus CABG*

Endpoint	Effect	95% CI	p ass	p het (I^2)	k	n
1 year event	RR=1.25	0.75;2.09	0.3934	1.0000 (0.00)	1	510
1 year revascularization	RR=5.31	1.99;14.16	0.0000	1.0000 (0.00)	1	510
long term cardiovascular events	RR=1.39	1.14;1.68	0.0000	1.0000 (0.00)	1	1900
long term death	RR=1.36	1.05;1.77	0.0208	1.0000 (1.00)	1	1900
2 yr MACE	RR=1.11	0.87;1.42	0.3873	1.0000 (0.00)	1	1900

CI: confidence interval; p ass: p-value of association test; p het: p-value of the heterogeneity test; k: number of trials; n: total number of patients; ES: effect size; I^2: inconsistance degree

16 Ongoing studies of PCI

Only one ongoing study was identified. A brief description of this trial is given table 16.1

Table 16.1: *Ongoing studies for PCI*

Study	Description
VA CARDS NCT00326196	percutaneous coronary stenting with drug eluding stents **vs.** CABG angiographically significant coronary artery disease in diabetes

17 Excluded studies for PCI

No trial was excluded.

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References

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