Myocardial revascularization for coronary artery disease in single vessel disease

A systematic review and meta-analysis of randomized clinical trials

2017 - 7 - 1

This report should be referenced as follows:
TrialResults-center.org; Results of all major randomized clinical trials about Myocardial revascularization for coronary artery disease in single vessel disease.

Contents

0.1 Synthesis of the meta-analysis results

We found 10 trials concerning PCI.
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).
Reports of 10 trials (including 1,291 patients) were identified .
Among these comparisons, one trial are about angioplasty,two about balloon angioplasty,one about PCI withdrug-eluting stents,one about PCI withsirolimus ES and 5 about stent.
No trial was excluded on grounds of potentially flawed methodology or incomplete presentation of results. No ongoing trial was found.

Angioplasty

Results obtained with angioplasty for all the endpoints with data in at least one trial are summarized table 1.

Table 1: *Results summary - Angioplasty*

Benefit	Harmful	No evidence
	Angioplasty versus MIDCAB	

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

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

Balloon angioplasty

Results obtained with balloon angioplasty for all the endpoints with data in at least one trial are summarized table 2.

Table 2: *Results summary - Balloon angioplasty*

Benefit	Harmful	No evidence
	Balloon angioplasty versus CABG	
	↑ CABG RR=10.67† [2.03;56.04] k=2	→ cardiac death or MI RR=3.49^{NS} [0.99;12.28] k=2 → all cause death RR=2.29^{NS} [0.42;12.54] k=2

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

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

PCI withdrug-eluting stents

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

Table 3: *Results summary - PCI withdrug-eluting stents*

Benefit	Harmful	No evidence
	PCI withdrug-eluting stents versus CABG	

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

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

PCI withsirolimus ES

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

Table 4: *Results summary - PCI withsirolimus ES*

Benefit	Harmful	No evidence
	PCI withsirolimus ES versus MIDCAB	

* $p < 0.05$; † $p < 0.01$; ¶ $p < 0.001$ 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 5.

Table 5: *Results summary - Stent*

Benefit	Harmful	No evidence
	Stent versus E-ACAB	
	↑ 6 months events RR=22.00* [1.33;364.29] k=1	→ 6 months death RR=1.00^{NS} [0.02;49.42] k=1 → 6 months MI RR=1.00^{NS} [0.02;49.42] k=1
	Stent versus MIDCAB	
	↑ 6 months events RR=2.06† [1.27;3.33] k=2 ↑ 1 year event RR=3.00* [1.04;8.68] k=1 ↑ RR=3.24¶ [1.61;6.54] k=2 ↑ long term cardiovascular events RR=3.24¶ [1.61;6.54] k=2 ↑ 1 year death from any cause RR=3.00* [1.04;8.68] k=1	→ 6 months death RR=0.62^{NS} [0.14;2.72] k=3 → 6 months MI RR=1.21^{NS} [0.32;4.54] k=3 → long term death RR=0.10^{NS} [0.00;8.53] H k=2

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

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

1 Introduction

1.1 Aim of the report

This report review all the randomized clinical trials of myocardial revascularization for the treatment of coronary artery disease in single vessel disease.

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 coronary artery disease in single vessel disease.

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.

1.3 Inclusion criteria

Participants only those studies were included in which the participants had been diagnosed as having established coronary artery disease.

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 6 months death, 6 months MI, 6 months events, long term cardiovascular events, CABG, Cardiac death or MI, Long term death, , All cause death, 1 year death from any cause, 1 year event, .

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 **??** to **??**, listed by therapeutic class. The therapeutic classes included 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.

2 Overview of PCI

2.1 Included trials

A total of 10 randomized comparisons which enrolled 1291 patients were identified. In all, 1 randomized comparison concerned angioplasty , two balloon angioplasty , one PCI withdrug-eluting stents , one PCI withsirolimus ES and 5 stent.
The detailed descriptions of trials and meta-analysis results is given in section 3 (page 23) for angioplasty, in section 4 (page 29) for balloon angioplasty, in section 5 (page 37) for PCI withdrug-eluting stents, in section 6 (page 42) for PCI withsirolimus ES and in section 7 (page 48) for stent.

The average study size was 129 patients (range 53 to 220). The first study was published in 1994, and the last study was published in 2009.
All trials were open-label in design. All included studies were reported in English language. We did not found any unpublished trial.
The table 2.1 (page 13) 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 PCI provide the results listed in tables 2.2 to 2.6 (page 16) and in the following graphs.

2.2.1 Angioplasty

Data were insufficient to compare **angioplasty** to **MIDCAB**. There was an eligible trial but it did not provided sufficient information about the endpoints considered by this meta-analysis.

2.2.2 Balloon angioplasty

Balloon angioplasty was inferior to **CABG** in terms of CABG (RR=10.67, 95% CI 2.03 to 56.04, p=0.0052, 2 trials). No significant difference was found on cardiac death or MI (RR=3.49, 95% CI 0.99 to 12.28, p=0.0518, 2 trials)and all cause death (RR=2.29, 95% CI 0.42 to 12.54, p=0.3407, 2 trials).

2.2.3 PCI withdrug-eluting stents

Data were insufficient to compare **PCI withdrug-eluting stents** to **CABG**. There was an eligible trial but it did not provided sufficient information about the endpoints considered by this meta-analysis.

2.2.4 PCI withsirolimus ES

Data were insufficient to compare **PCI withsirolimus ES** to **MIDCAB**. There was an eligible trial but it did not provided sufficient information about the endpoints considered by this meta-analysis.

2.2.5 Stent

Stent was inferior to **E-ACAB** in terms of 6 months events (RR=22.00, 95% CI 1.33 to 364.29, p=0.0309, 1 trial). No significant difference was found on 6 months death (RR=1.00, 95% CI 0.02 to 49.42, p=1.0000, 1 trial)and 6 months MI (RR=1.00, 95% CI 0.02 to 49.42, p=1.0000, 1 trial).

Stent was inferior to **MIDCAB** in terms of 6 months events (RR=2.06, 95% CI 1.27 to 3.33, p=0.0035, 2 trials), 1 year event (RR=3.00, 95% CI 1.04 to 8.68, p=0.0428, 1 trial), (RR=3.24, 95% CI 1.61 to 6.54, p=0.0000, 2 trials), long term cardiovascular events (RR=3.24, 95% CI 1.61 to 6.54, p=0.0000, 2 trials)and 1 year death from any cause (RR=3.00, 95% CI 1.04 to 8.68, p=0.0428, 1 trial). No significant difference was found on 6 months death (RR=0.62, 95% CI 0.14 to 2.72, p=0.5279, 3 trials), 6 months MI (RR=1.21, 95% CI 0.32 to 4.54, p=0.7750, 3 trials)and long term death (RR=0.10, 95% CI 0.00 to 8.53, p=0.3072, 2 trials)with a random effect model in reason of a heterogeneity (Het. p=0.0216)

Table 2.1: *Main study characteristics - PCI*

Trial	Patients	Treatments	Trial design and method
Angioplasty			
Angioplasty versus MIDCAB			
AMIST (Reeves), 2004 [1] n = 50 vs. 50	single-vessel disease (at least 50% stenosis) of the left anterior descending coronary artery (LAD).	percutaneous transluminal coronary angioplasty (PTCA) with or without stenting **versus** minimally invasive direct coronary artery bypass grafting (MIDCAB) arterial grafts: 100% stent (%): 97.9%	open parallel groups Primary endpoint: cardiac-related events multicentre, England
Balloon angioplasty			
Balloon angioplasty versus CABG			
MASS, 1995 [1] n = 72 vs. 70	patients with stable angina,normal ventricular function and a proximal stenosis of the leftanterior descending coronary artery >80%	percutaneous transluminal coronaryangioplasty **versus** mammary bypass surgery	open Brazil
Lausanne, 1994 [2] n = 68 vs. 66	patients with isolated proximal left anterior descending artery stenosis, conserved left ventricular function, and documented ischaemia	transluminal coronary angioplasty **versus** coronary artery bypass grafting	open Switzerland
PCI withdrug-eluting stents			
PCI withdrug-eluting stents versus CABG			

continued...

Trial	Patients	Treatments	Trial design and method
Hong, 2005 [1] n = 119 vs. 70	proximal left anterior descending (LAD) coronary artery stenosis	drug-eluting stents **versus** invasive direct coronary artery bypass (MIDCAB) surgery arterial grafts: 100% stent (%): 100%	open parallel groups
PCI withsirolimus ES			
PCI withsirolimus ES versus MIDCAB			
Thiele, 2009 [1] n = 65 vs. 65	isolated LAD disease	sirolimus-eluting stent **versus** MIDCAB surgery arterial grafts: 92% stent (%): 100%	open parallel groups Primary endpoint: cardiac death, MI, and need for PCI single center, Germany
Stent			
Stent versus E-ACAB			
Cisowski, 0 n = 50 vs. 50	single vessel disease ACC/AHA A or B lesion in proximal LAD Angina CCS II or higher Lesion diameter 3 mm orgreater/length 20mm or greater	tristar, Tera, Penta (Guidant) (Cordis) **versus** endoscopic atraumatic coronary artery bypass grafting arterial grafts: 100% stent (%): 100%	open parallel group Single center, Poland
Stent versus MIDCAB			
Diegeler, 2002 [1, 2] n = 110 vs. 110	single vessel disease Lesion =75% stenosis in proximal LAD or between origin of left circumflex and 1st septal branch	various stents **versus** minimally invasive direct coronary artery bypass (off-pump proceedure) arterial grafts: 100% stent (%): 100%	open parallel group Primary endpoint: major adverse cardiac events Multicentre, Germany

continued...

Trial	Patients	Treatments	Trial design and method
Drenth, 2002 [3, 4, 5] n = 51 vs. 51	single vessel disease Angina II Lesion (Grade B2 or C) of proximal LAD Suitable for CABG or stenting	stent type not reported **versus** minimally invasive direct coronary artery bypass (off-pump proceedure arterial grafts: 100% stent (%): 100%	open parallel group Primary endpoint: major Adverse Cardiac and Cerebrovascular Events Single centre, Netherlands
Grip, 2001 [6] n = 28 vs. 25	single vessel disease engaging LAD Stable or unstable angina	stent type not reported **versus** minimally invasive direct coronary artery bypass (off-pump proceedure) arterial grafts: NA stent (%): NA	open parallel group Sweden
SIMA, 2000 [7] n = 62 vs. 59	single vessel disease Symptomatic or silent ischaemia 1 LAD lesion Ejection fraction >45% Vessel >3.0mm	any CE marked, but Palmaz-Schatz recommended **versus** conventional CABG or minimally invasive direct coronary artery bypass (off-pump proceedure) (10% of surgical procedures arterial grafts: 98% stent (%): 100%	open parallel group Primary endpoint: death, myocardial infarction, revascularization Multicentre, Europe

Table 2.2: *Summary of all results for angioplasty*

Endpoint	Effect	95% CI	p ass	p het (I^2)	k	n
angioplasty versus MIDCAB						
No data were presented in the trial identified						

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 2.3: *Summary of all results for balloon angioplasty*

Endpoint	Effect	95% CI	p ass	p het (I^2)	k	n
balloon angioplasty versus CABG						
cardiac death or MI	RR=3.49	0.99;12.28	0.0518	0.7031 (0.00)	2	276
CABG	RR=10.67	2.03;56.04	0.0052	0.6060 (0.00)	2	276
all cause death	RR=2.29	0.42;12.54	0.3407	0.4383 (0.00)	2	276

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 2.4: *Summary of all results for PCI withdrug-eluting stents*

Endpoint	Effect	95% CI	p ass	p het (I^2)	k	n
PCI withdrug-eluting stents versus CABG						
No data were presented in the trial identified						

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 2.5: *Summary of all results for PCI withsirolimus ES*

Endpoint	Effect	95% CI	p ass	p het (I^2)	k	n
PCI withsirolimus ES versus MIDCAB						
No data were presented in the trial identified						

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 2.6: *Summary of all results for stent*

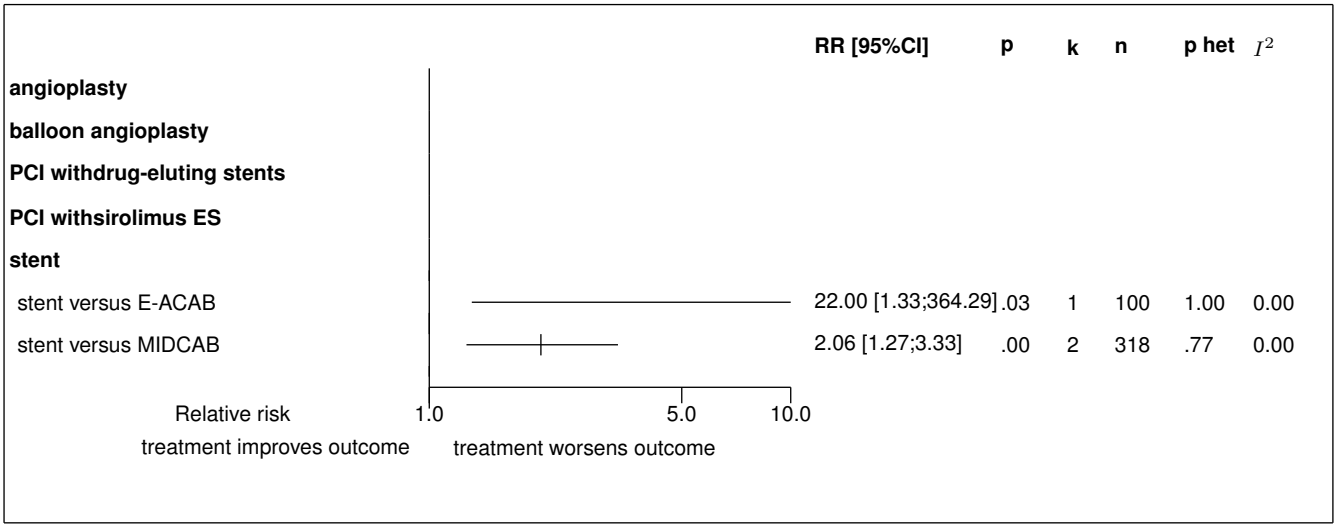
Endpoint	Effect	95% CI	p ass	p het (I^2)	k	n
stent versus E-ACAB						
6 months events	RR=22.00	1.33;364.29	0.0309	1.0000 (0.00)	1	100

continued...

Endpoint	Effect	95% CI	p ass	p het	k	n
6 months death	RR=1.00	0.02;49.42	1.0000	1.0000 (0.00)	1	100
6 months MI	RR=1.00	0.02;49.42	1.0000	1.0000 (0.00)	1	100
stent versus MIDCAB						
6 months events	RR=2.06	1.27;3.33	0.0035	0.7664 (0.00)	2	318
1 year event	RR=3.00	1.04;8.68	0.0428	1.0000 (0.00)	1	102
	RR=3.24	1.61;6.54	0.0000	0.3771 (0.00)	2	223
6 months death	RR=0.62	0.14;2.72	0.5279	0.7390 (0.00)	3	371
6 months MI	RR=1.21	0.32;4.54	0.7750	0.2578 (0.26)	3	371
long term cardiovascular events	RR=3.24	1.61;6.54	0.0000	0.3771 (0.00)	2	223
1 year death from any cause	RR=3.00	1.04;8.68	0.0428	1.0000 (0.00)	1	102
long term death	RR=0.10 [1]	0.00;8.53	0.3072	0.0216 (0.81) †	2	223

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

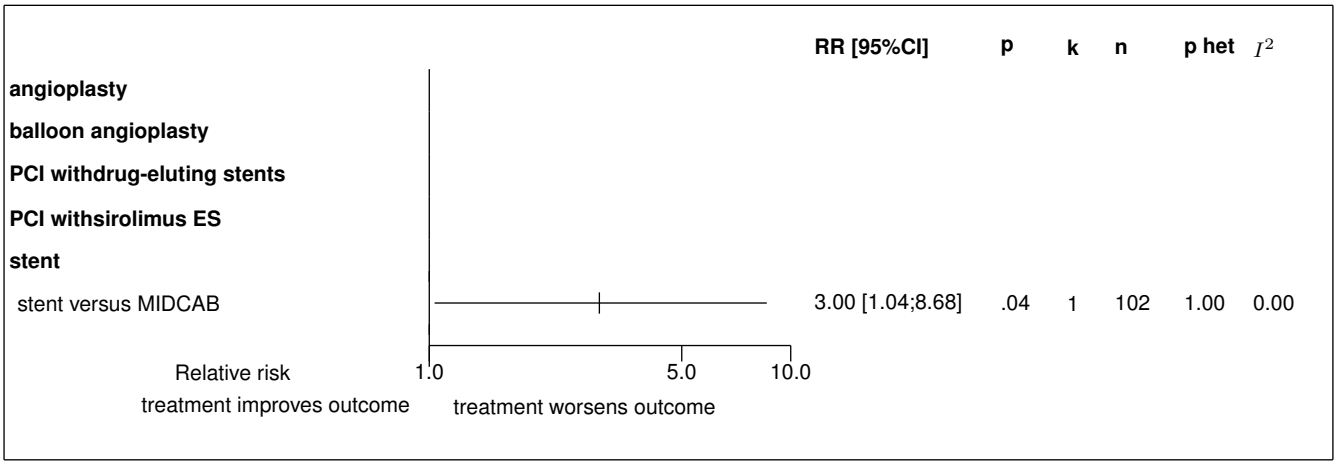
Figure 2.1: *Forest's plot for 6 months events*



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

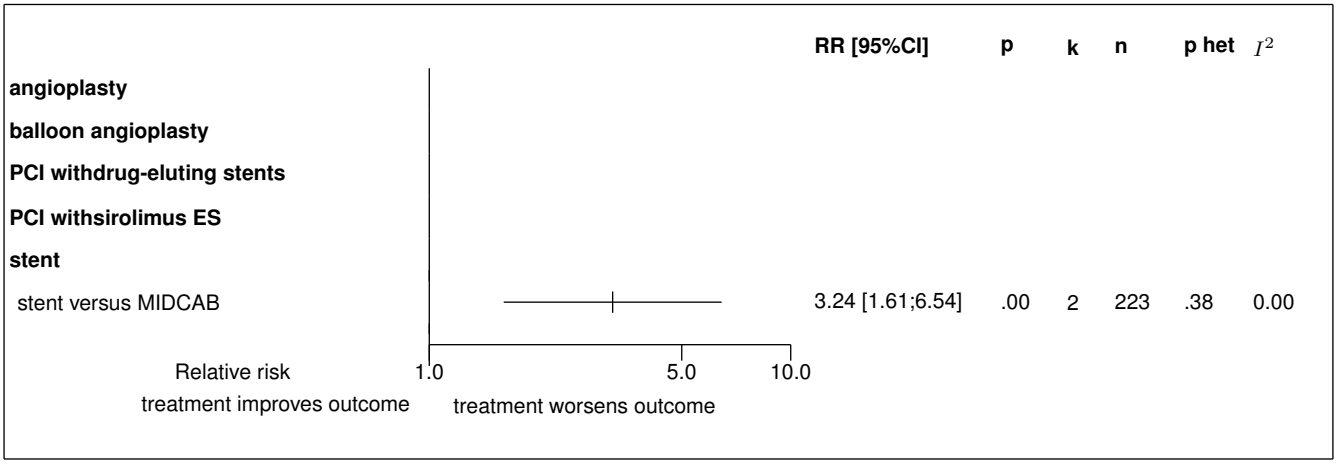
[1] with a random model ($\tau^2 = NaN$). The results with a fixed effect model was RRFE=0.10 95% CI 0.01;0.69

Figure 2.2: *Forest's plot for 1 year event*



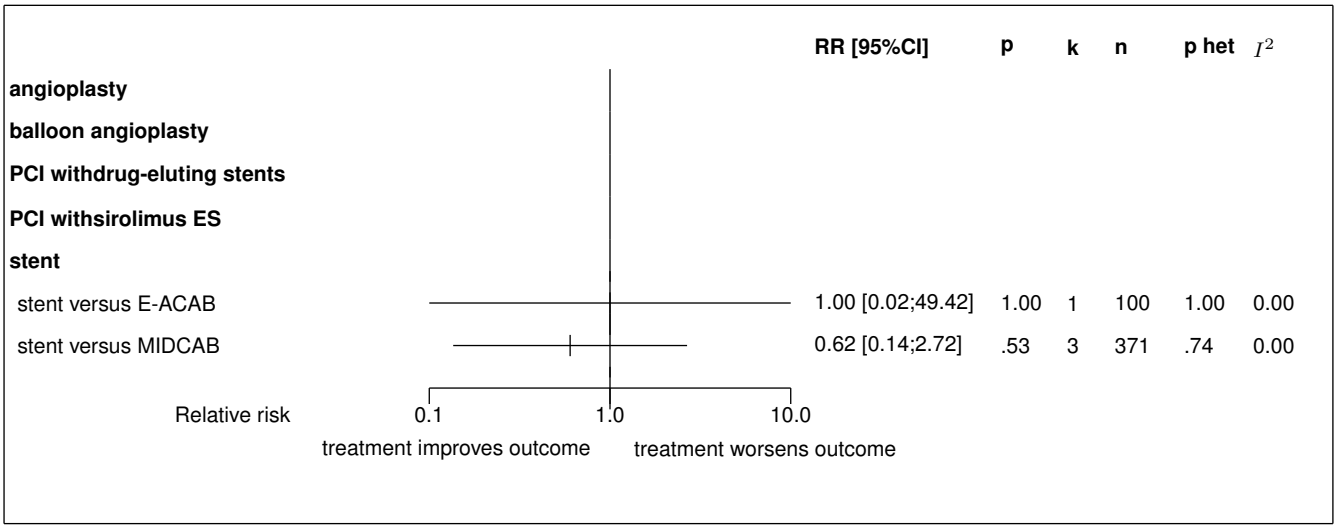
Results obtained with a fixed effect model except in case of heterogenity where a random model was used
RR: relative risk; 95% CI: 95% confidence interval; p: p-value of the association test; k: number of trials; n: total number of patients involving in the pooled trials; p het: p-value of the hetereogenity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

Figure 2.3: *Forest's plot for*



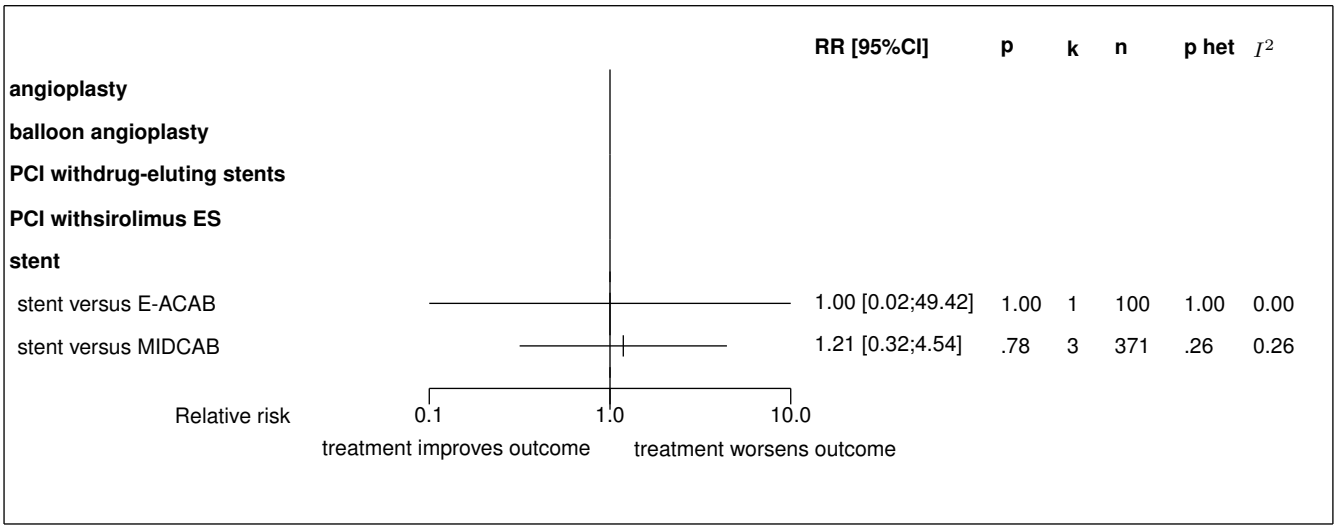
Results obtained with a fixed effect model except in case of heterogenity where a random model was used
RR: relative risk; 95% CI: 95% confidence interval; p: p-value of the association test; k: number of trials; n: total number of patients involving in the pooled trials; p het: p-value of the hetereogenity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

Figure 2.4: *Forest's plot for 6 months death*



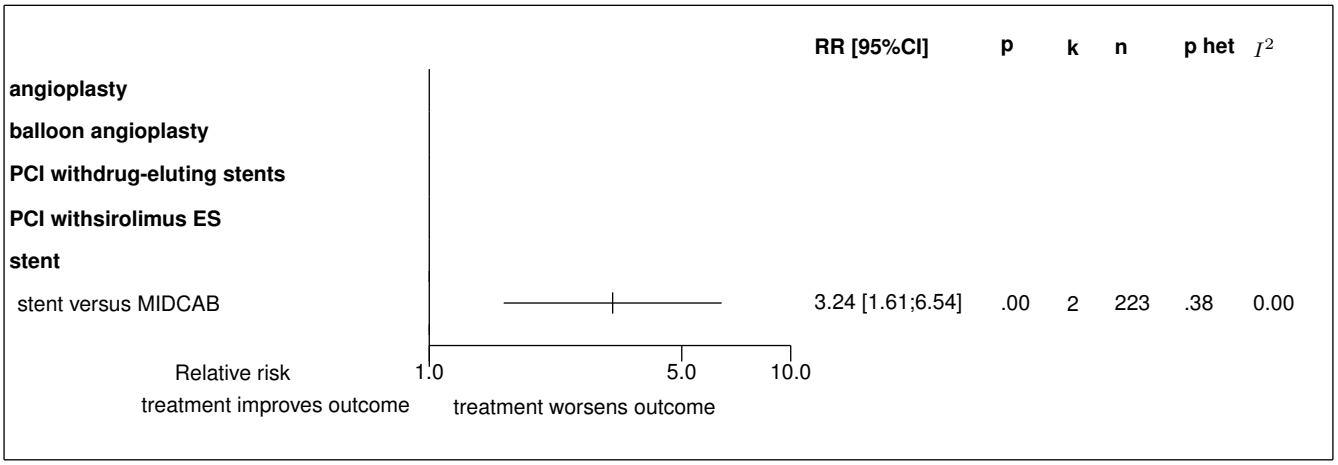
Results obtained with a fixed effect model except in case of heterogenity where a random model was used
RR: relative risk; 95% CI: 95% confidence interval; p: p-value of the association test; k: number of trials; n: total number of patients involving in the pooled trials; p het: p-value of the hetereogenity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

Figure 2.5: *Forest's plot for 6 months MI*



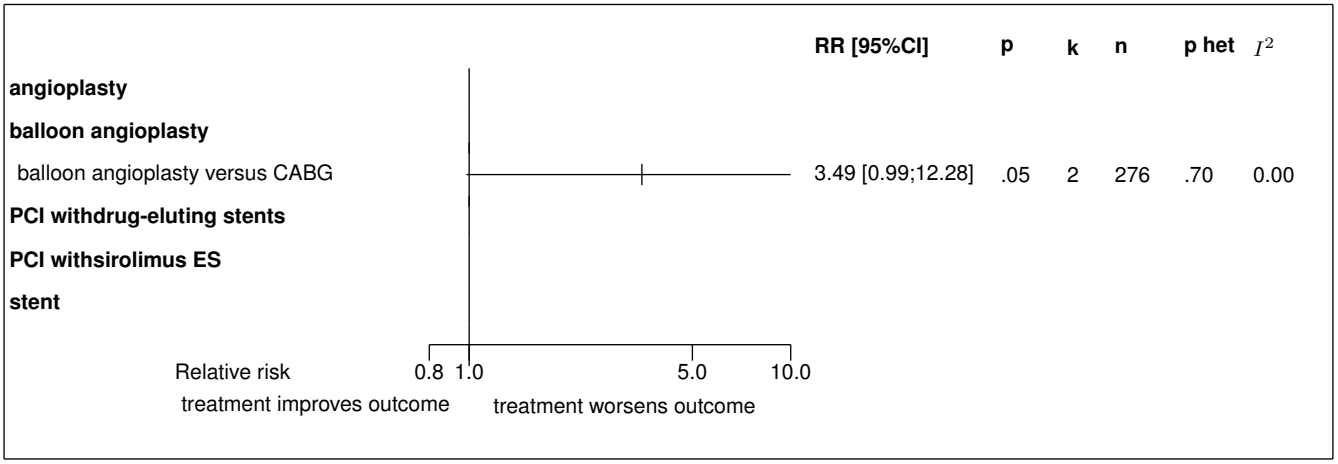
Results obtained with a fixed effect model except in case of heterogenity where a random model was used
RR: relative risk; 95% CI: 95% confidence interval; p: p-value of the association test; k: number of trials; n: total number of patients involving in the pooled trials; p het: p-value of the hetereogenity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

Figure 2.6: *Forest's plot for long term cardiovascular events*



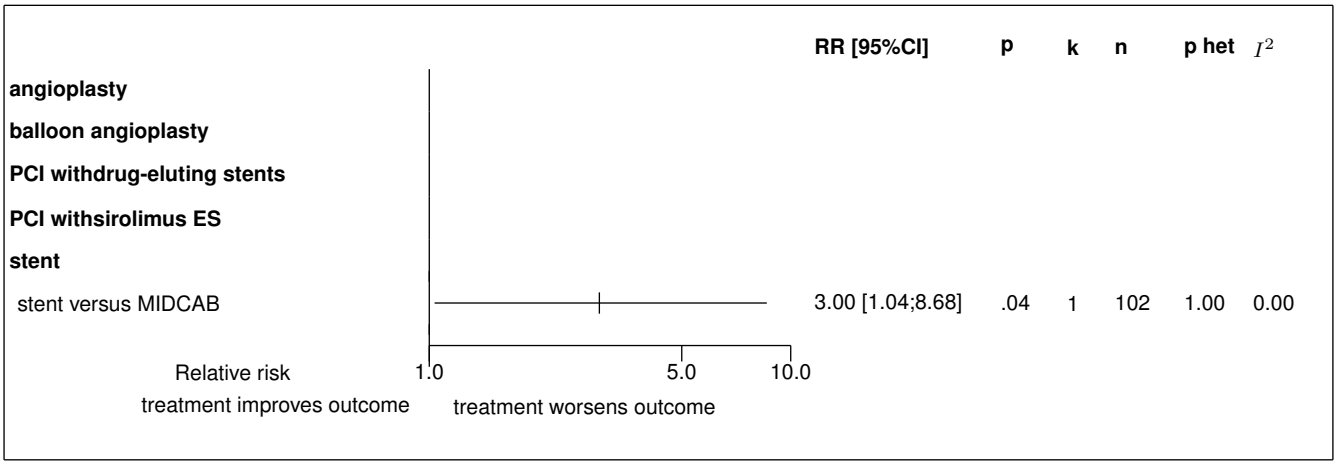
Results obtained with a fixed effect model except in case of heterogenity where a random model was used
RR: relative risk; 95% CI: 95% confidence interval; p: p-value of the association test; k: number of trials; n: total number of patients involving in the pooled trials; p het: p-value of the hetereogenity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

Figure 2.7: *Forest's plot for cardiac death or MI*



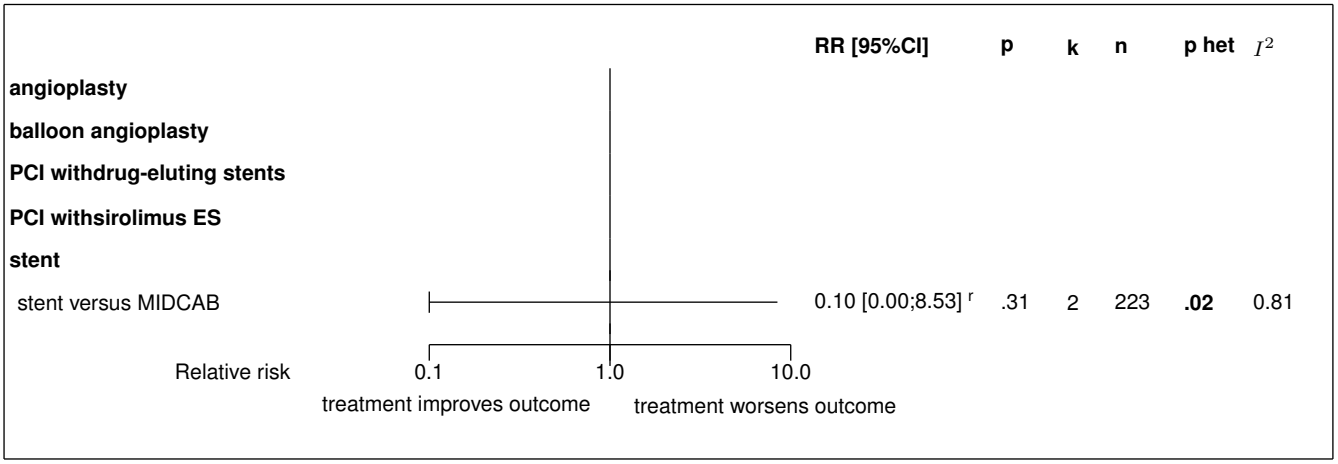
Results obtained with a fixed effect model except in case of heterogenity where a random model was used
RR: relative risk; 95% CI: 95% confidence interval; p: p-value of the association test; k: number of trials; n: total number of patients involving in the pooled trials; p het: p-value of the hetereogenity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

Figure 2.8: *Forest's plot for 1 year death from any cause*



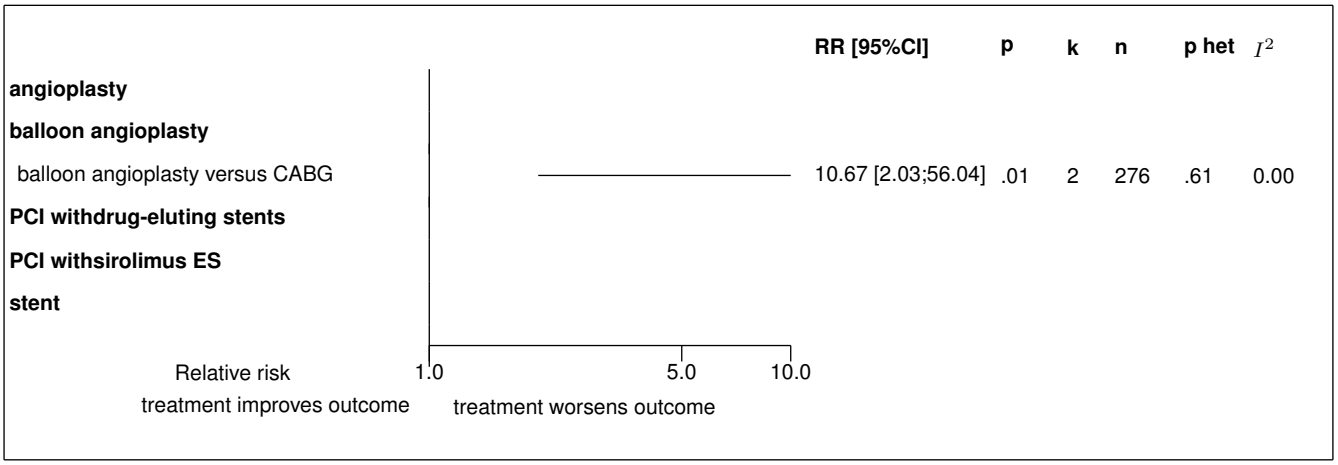
Results obtained with a fixed effect model except in case of heterogenity where a random model was used
RR: relative risk; 95% CI: 95% confidence interval; p: p-value of the association test; k: number of trials; n: total number of patients involving in the pooled trials; p het: p-value of the hetereogenity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

Figure 2.9: *Forest's plot for long term death*



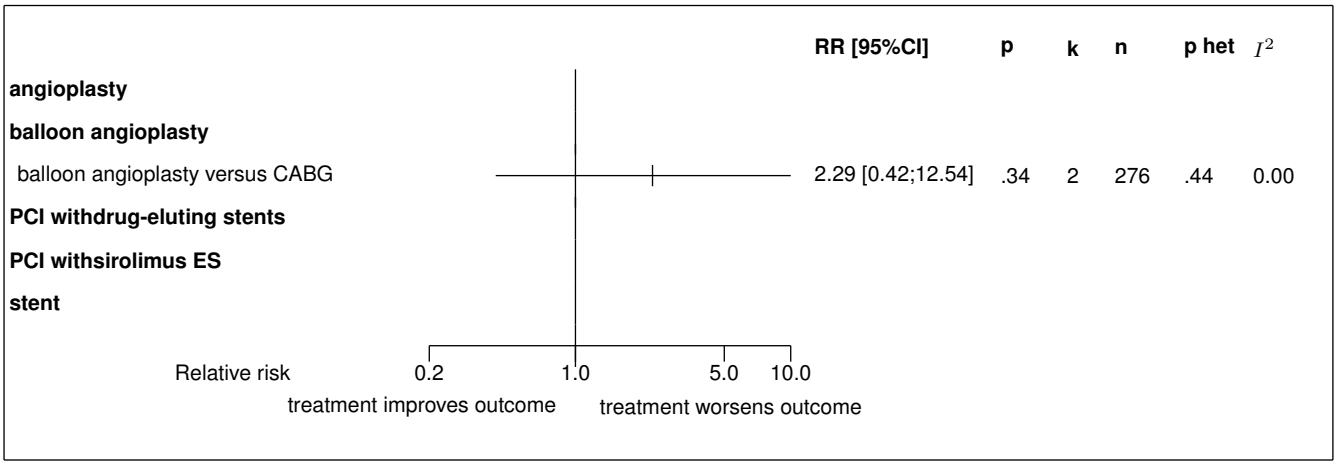
Results obtained with a fixed effect model except in case of heterogenity where a random model was used
RR: relative risk; 95% CI: 95% confidence interval; p: p-value of the association test; k: number of trials; n: total number of patients involving in the pooled trials; p het: p-value of the hetereogenity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

Figure 2.10: *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

Figure 2.11: *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

3 Detailed results for angioplasty

3.1 Available trials

Only one trial which randomized 100 patients was identified: it compared angioplasty with MIDCAB.
This trial included 100 patients and was published in 2004.
This trial was open-label in design.
It was reported in English language.
data was reported in trials;
Following tables 3.1 (page 23), 3.2 (page 23), 3.4 (page 25), and 3.3 (page 23) summarized the main characteristics of the trial including in this systematic review of randomized trials of angioplasty.

Table 3.1: *Treatment description - PCI - angioplasty*

Trial	Studied treatment	Control treatment
Angioplasty versus MIDCAB		
AMIST (Reeves) (2004) [1]	percutaneous transluminal coronary angioplasty (PTCA) with or without stenting	minimally invasive direct coronary artery bypass grafting (MIDCAB)

Table 3.2: *Descriptions of participants - PCI - angioplasty*

Trial	Patients
Angioplasty versus MIDCAB	
AMIST (Reeves) (2004) [1]	Single-vessel disease (at least 50% stenosis) of the left anterior descending coronary artery (LAD).

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

Trial	Design	Duration	Centre	Primary end-point
Angioplasty versus MIDCAB				
AMIST (Reeves), 2004 [1] n=100	Parallel groups open confirmatory trial at risk of bias	12 months	England multicentre	cardiac-related events

continued...

Trial	Design	Duration	Centre	Primary endpoint

Table 3.4: *Trial characteristics - PCI - angioplasty*

Trial	Age (mean, year)	Men (%)	Ejection fraction (%)	Extent of Disease	arterial grafts	stent (%)
Angioplasty versus MIDCAB						
AMIST (Reeves), 2004 [1]				single vessel disease	100%	97.9%

3.2 Meta-analysis results

The results are detailed in table 3.5 (page 26). This table is followed by the Forest's plot corresponding to each endpoint.

Angioplasty versus MIDCAB

No data were presented in the 1 trial identified

Table 3.5: *Results details - PCI - angioplasty*

Comparison Endpoint	Effect	95% CI	p ass	p het	k	n
angioplasty versus MIDCAB						
No data were presented in the trial identified						

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

References

[1] Reeves BC, Angelini GD, Bryan AJ, Taylor FC, Cripps T, Spyt TJ, Samani NJ, Roberts JA, Jacklin P, Seehra HK, Culliford LA, Keenan DJ, Rowlands DJ, Clarke B, Stanbridge R, Foale R. A multi-centre randomised controlled trial of minimally invasive direct coronary bypass grafting versus percutaneous transluminal coronary angioplasty with stenting for proximal stenosis of the left anterior descending coronary artery. Health Technol Assess 2004;8:1-43. [PMID=15080865]

3.3 Individual trial summaries

Table 3.6: *AMIST (Reeves), 2004 - Trial synopsis*

Trial details	Patients	Treatments	Outcomes
n=100 (50 vs. 50) **Follow-up duration:** 12 months **Study design:** Randomized controlled trial Parallel groups Open Confirmatory trial at risk of bias England, multicentre	Single-vessel disease (at least 50% stenosis) of the left anterior descending coronary artery (LAD).	**Studied treatment:** percutaneous transluminal coronary angioplasty (PTCA) with or without stenting **Control treatment:** minimally invasive direct coronary artery bypass grafting (MIDCAB)	

Reference

Reeves BC, Angelini GD, Bryan AJ, Taylor FC, Cripps T, Spyt TJ, Samani NJ, Roberts JA, Jacklin P, Seehra HK, Culliford LA, Keenan DJ, Rowlands DJ, Clarke B, Stanbridge R, Foale R. A multi-centre randomised controlled trial of minimally invasive direct coronary bypass grafting versus percutaneous transluminal coronary angioplasty with stenting for proximal stenosis of the left anterior descending coronary artery. Health Technol Assess 2004;8:1-43 [PMID=15080865]

4 Detailed results for balloon angioplasty

4.1 Available trials

A total of 2 RCTs which randomized 276 patients were identified: all compared balloon angioplasty with CABG.
The average study size was 138 patients (range 134 to 142). The first study was published in 1994, and the last study was published in 1995.
All trials were open-label in design. All included studies were reported in English language. We did not found any unpublished trial.
CABG data was reported in 2 trials; 2 trials reported data on cardiac death or MI; and 2 trials reported data on all cause death.
Following tables 4.1 (page 29), 4.2 (page 29), 4.4 (page 31), and 4.3 (page 30) summarized the main characteristics of the trials including in this systematic review of randomized trials of balloon angioplasty.

Table 4.1: *Treatment description - PCI - balloon angioplasty*

Trial	Studied treatment	Control treatment
Balloon angioplasty versus CABG		
MASS (1995) [1]	percutaneous transluminal coronaryangioplasty	mammary bypass surgery
Lausanne (1994) [2]	transluminal coronary angioplasty	Coronary artery bypass grafting

Table 4.2: *Descriptions of participants - PCI - balloon angioplasty*

Trial	Patients
Balloon angioplasty versus CABG	
MASS (1995) [1]	Patients with stable angina,normal ventricular function and a proximal stenosis of the leftanterior descending coronary artery >80%
Lausanne (1994) [2]	Patients with isolated proximal left anterior descending artery stenosis, conserved left ventricular function, and documented ischaemia

Table 4.3: *Design and methodological quality of trials - PCI - balloon angioplasty*

Trial	Design	Duration	Centre	Primary end-point
Balloon angioplasty versus CABG				
MASS, 1995 [1] n=142	open	3.2 y	Brazil	
Lausanne, 1994 [2] n=134	open	3.2 y	Switzerland	

Table 4.4: *Trial characteristics - PCI - balloon angioplasty*

Trial
Balloon angioplasty versus CABG
MASS, 1995 [1]
Lausanne, 1994 [2]

4.2 Meta-analysis results

The results are detailed in table 4.5 (page 32). This table is followed by the Forest's plot corresponding to each endpoint.

Balloon angioplasty versus CABG

All the 2 studies had extractable data about the number of participants with **cardiac death or MI**. When pooled together, there was no statistically significant difference between the groups in cardiac death or MI, with a RR of 3.49 (95% CI 0.99 to 12.28, p=0.0518). No heterogeneity was detected (p = 0.7031, I^2 = 0.00%).
All the 2 studies had extractable data about the number of participants with **CABG**. The analysis detected a statistically significant difference in favor of CABG in CABG, with a RR of 10.67 (95% CI 2.03 to 56.04, p=0.0052). No heterogeneity was detected (p = 0.6060, I^2 = 0.00%).
All the 2 studies had extractable data about the number of participants with **all cause death**. When pooled together, there was no statistically significant difference between the groups in all cause death, with a RR of 2.29 (95% CI 0.42 to 12.54, p=0.3407). No heterogeneity was detected (p = 0.4383, I^2 = 0.00%).

Table 4.5: *Results details - PCI - balloon angioplasty*

Comparison Endpoint	Effect	95% CI	p ass	p het	k	n
balloon angioplasty versus CABG						
cardiac death or MI	RR=3.49	[0.99;12.28]	0.0518	0.7031 (I^2=0.00)	2	276
CABG	RR=10.67	[2.03;56.04]	0.0052	0.6060 (I^2=0.00)	2	276
all cause death	RR=2.29	[0.42;12.54]	0.3407	0.4383 (I^2=0.00)	2	276

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 4.1: *Forest's plot for cardiac death or MI*

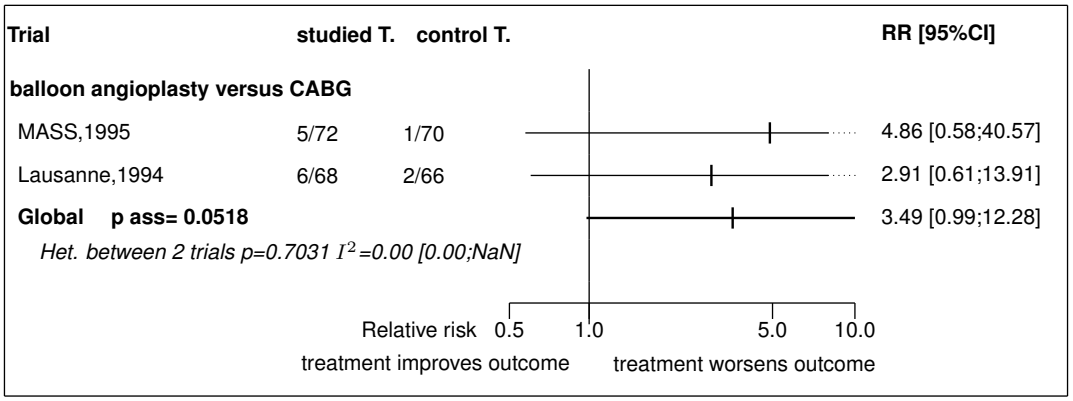


Figure 4.2: *Forest's plot for CABG*

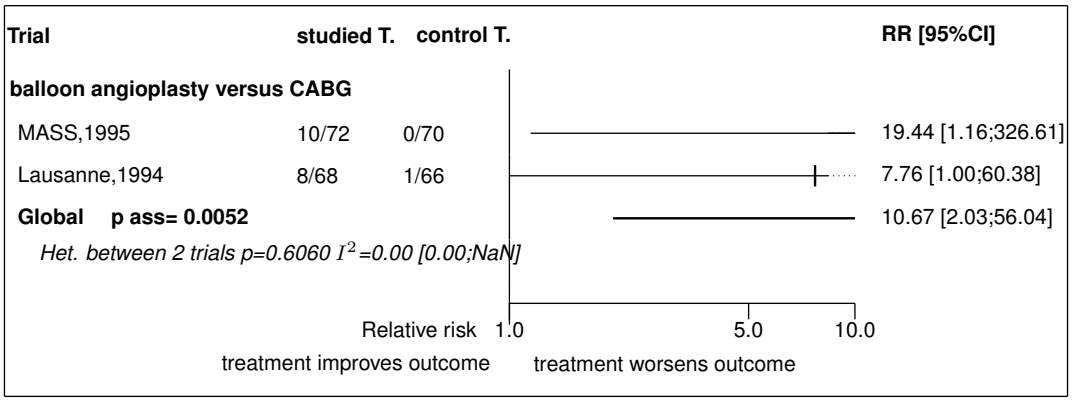
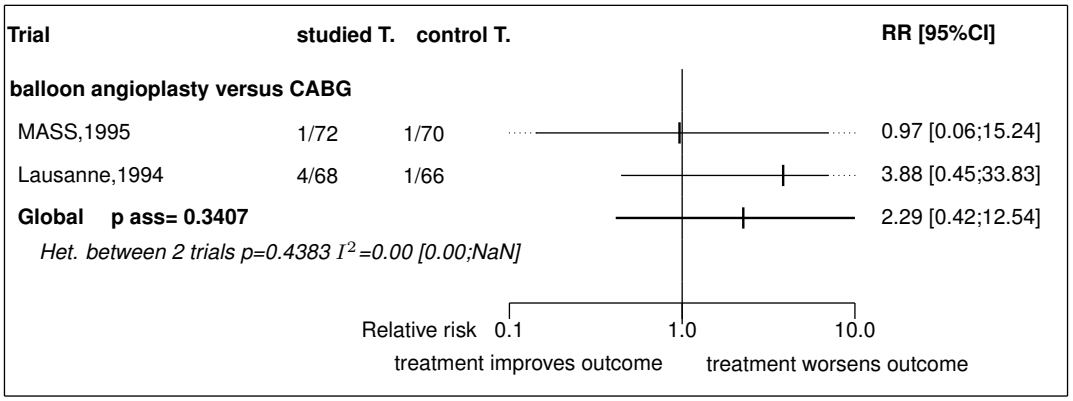


Figure 4.3: *Forest's plot for all cause death*



References

[1] Hueb WA, Bellotti G, de Oliveira SA, Arie S, de Albuquerque CP, Jatene AD, Pileggi F. The Medicine, Angioplasty or Surgery Study (MASS): a prospective, randomized trial of medical therapy, balloon angioplasty or bypass surgery for single proximal left anterior descending artery stenoses. J Am Coll Cardiol 1995 Dec;26:1600-5. [PMID=7594092]

[2] Goy JJ, Eeckhout E, Burnand B, Vogt P, Stauffer JC, Hurni M, Stumpe F, Ruchat P, Sadeghi H, Kappenberger L. Coronary angioplasty versus left internal mammary artery grafting for isolated proximal left anterior descending artery stenosis. Lancet 1994 Jun 11;343:1449-53. [PMID=7911175]

4.3 Individual trial summaries

Table 4.6: *MASS, 1995 - Trial synopsis*

Trial details	Patients	Treatments	Outcomes
n=142 (72 vs. 70) **Follow-up duration:** 3.2 y **Study design:** Randomized controlled trial Open Brazil	Patients with stable angina,normal ventricular function and a proximal stenosis of the leftanterior descending coronary artery >80%	**Studied treatment:** percutaneous transluminal coronaryangioplasty **Control treatment:** mammary bypass surgery	Cardiac death or MI RR=4.86 [0.58;40.57]

Reference

Hueb WA, Bellotti G, de Oliveira SA, Arie S, de Albuquerque CP, Jatene AD, Pileggi F. The Medicine, Angioplasty or Surgery Study (MASS): a prospective, randomized trial of medical therapy, balloon angioplasty or bypass surgery for single proximal left anterior descending artery stenoses. J Am Coll Cardiol 1995 Dec;26:1600-5 [PMID=7594092]

Table 4.7: *Lausanne, 1994 - Trial synopsis*

Trial details	Patients	Treatments	Outcomes
n=134 (68 vs. 66) **Follow-up duration:** 3.2 y **Study design:** Randomized controlled trial Open Switzerland	Patients with isolated proximal left anterior descending artery stenosis, conserved left ventricular function, and documented ischaemia	**Studied treatment:** transluminal coronary angioplasty **Control treatment:** Coronary artery bypass grafting	Cardiac death or MI RR=2.91 [0.61;13.91]

Reference

Goy JJ, Eeckhout E, Burnand B, Vogt P, Stauffer JC, Hurni M, Stumpe F, Ruchat P, Sadeghi H, Kappenberger L. Coronary angioplasty versus left internal mammary artery grafting for isolated proximal left anterior descending artery stenosis. Lancet 1994 Jun 11;343:1449-53 [PMID=7911175]

5 Detailed results for PCI withdrug-eluting stents

5.1 Available trials

Only one trial which randomized 189 patients was identified: it compared PCI withdrug-eluting stents with CABG.
This trial included 189 patients and was published in 2005.
This trial was open-label in design.
It was reported in English language.
data was reported in trials;
Following tables 5.1 (page 37), 5.2 (page 37), 5.4 (page 38), and 5.3 (page 37) summarized the main characteristics of the trial including in this systematic review of randomized trials of PCI withdrug-eluting stents.

Table 5.1: *Treatment description - PCI - PCI withdrug-eluting stents*

Trial	Studied treatment	Control treatment
PCI withdrug-eluting stents versus CABG		
Hong (2005) [1]	drug-eluting stents	invasive direct coronary artery bypass (MIDCAB) surgery

Table 5.2: *Descriptions of participants - PCI - PCI withdrug-eluting stents*

Trial	Patients
PCI withdrug-eluting stents versus CABG	
Hong (2005) [1]	Proximal left anterior descending (LAD) coronary artery stenosis

Table 5.3: *Design and methodological quality of trials - PCI - PCI withdrug-eluting stents*

Trial	Design	Duration	Centre	Primary end-point
PCI withdrug-eluting stents versus CABG				
Hong, 2005 [1] n=189	Parallel groups open confirmatory trial at risk of bias	9 months		

Table 5.4: *Trial characteristics - PCI - PCI withdrug-eluting stents*

Trial	Age (mean, year)	Men (%)	Ejection fraction (%)	Extent of Disease	arterial grafts	stent (%)
PCI withdrug-eluting stents versus CABG						
Hong, 2005 [1]				single vessel disease	100%	100%

5.2 Meta-analysis results

The results are detailed in table 5.5 (page 39). This table is followed by the Forest's plot corresponding to each endpoint.

PCI withdrug-eluting stents versus CABG

No data were presented in the 1 trial identified

Table 5.5: *Results details - PCI - PCI withdrug-eluting stents*

Comparison Endpoint	Effect	95% CI	p ass	p het	k	n
PCI withdrug-eluting stents versus CABG						
No data were presented in the trial identified						

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

References

[1] Hong SJ, Lim DS, Seo HS, Kim YH, Shim WJ, Park CG, Oh DJ, Ro YM. Percutaneous coronary intervention with drug-eluting stent implantation vs. minimally invasive direct coronary artery bypass (MIDCAB) in patients with left anterior descending coronary artery stenosis. Catheter Cardiovasc Interv 2005;64:75-81. [PMID=15619278]

5.3 Individual trial summaries

Table 5.6: *Hong, 2005 - Trial synopsis*

Trial details	Patients	Treatments	Outcomes
n=189 (119 vs. 70) **Follow-up duration:** 9 months **Study design:** Randomized controlled trial Parallel groups Open Confirmatory trial at risk of bias	Proximal left anterior descending (LAD) coronary artery stenosis	**Studied treatment:** drug-eluting stents **Control treatment:** invasive direct coronary artery bypass (MIDCAB) surgery	

Reference

Hong SJ, Lim DS, Seo HS, Kim YH, Shim WJ, Park CG, Oh DJ, Ro YM. Percutaneous coronary intervention with drug-eluting stent implantation vs. minimally invasive direct coronary artery bypass (MIDCAB) in patients with left anterior descending coronary artery stenosis. Catheter Cardiovasc Interv 2005;64:75-81 [PMID=15619278]

6 Detailed results for PCI withsirolimus ES

6.1 Available trials

Only one trial which randomized 130 patients was identified: it compared PCI withsirolimus ES with MIDCAB.
This trial included 130 patients and was published in 2009.
This trial was open-label in design.
It was reported in English language.
data was reported in trials;
Following tables 6.1 (page 42), 6.2 (page 42), 6.4 (page 44), and 6.3 (page 43) summarized the main characteristics of the trial including in this systematic review of randomized trials of PCI withsirolimus ES.

Table 6.1: *Treatment description - PCI - PCI withsirolimus ES*

Trial	Studied treatment	Control treatment
PCI withsirolimus ES versus MIDCAB		
Thiele (2009) [1]	sirolimus-eluting stent	MIDCAB surgery
	Concomittant treatment: fro PCI: aspirin (at least 100 mg/day, subsequently 100 mg/day indefinitely) and clopidogrel (600 mg orally, followed by 75 mg/day for at least 12 months); during the procedure heparin (60 U/kg body weight);for surgery : aspirin 100 mg/day indefinitely	

Table 6.2: *Descriptions of participants - PCI - PCI withsirolimus ES*

Trial	Patients	
PCI withsirolimus ES versus MIDCAB		
Thiele (2009) [1]	Isolated LAD disease	
	Inclusion criteria: age >18 years; isolated proximal LAD stenosis >50% (between origin of left circumflex artery and first septal perforator); symptomatic; presence of myocardial ischemia	**Exclusion criteria:** acute coronary syndrome; additional valvular heart disease requiring surgical intervention; previous interventional or surgical treatment for coronary artery disease or valvular heart disease; severe peripheral vascular disease; significant carotid disease needing treatment; end-stage renal disease on hemodialysis; overt congestive heart failure; upper gastrointestinal bleeding <4 weeks; contraindication to antiplatelet therapy; diseases with limited life expectancy; extreme obesity; total occlusions; involvement of left main trunk; stenosis of first diagonal branch; intramyocardial course of LAD; stenosis extending over a major diagonal branch; stenosis at any other location requiring treatment

Table 6.3: *Design and methodological quality of trials - PCI - PCI withsirolimus ES*

Trial	Design	Duration	Centre	Primary end-point
PCI withsirolimus ES versus MIDCAB				
Thiele, 2009 [1] n=130	Parallel groups open confirmatory trial at risk of bias	12 months	Germany single center	cardiac death, MI, and need for PCI

Table 6.4: *Trial characteristics - PCI - PCI withsirolimus ES*

Trial	Age (mean, year)	Men (%)	Ejection fraction (%)	Extent of Disease	arterial grafts	stent (%)
PCI withsirolimus ES versus MIDCAB						
Thiele, 2009 [1]				single vessel disease	92%	100%

6.2 Meta-analysis results

The results are detailed in table 6.5 (page 45). This table is followed by the Forest's plot corresponding to each endpoint.

PCI withsirolimus ES versus MIDCAB

No data were presented in the 1 trial identified

Table 6.5: *Results details - PCI - PCI withsirolimus ES*

Comparison Endpoint	Effect	95% CI	p ass	p het	k	n
PCI withsirolimus ES versus MIDCAB						
No data were presented in the trial identified						

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

References

[1] Thiele H, Neumann-Schniedewind P, Jacobs S, Boudriot E, Walther T, Mohr FW, Schuler G, Falk V. Randomized comparison of minimally invasive direct coronary artery bypass surgery versus sirolimus-eluting stenting in isolated proximal left anterior descending coronary artery stenosis. J Am Coll Cardiol 2009 Jun 23;53:2324-31. [PMID=19539141]

6.3 Individual trial summaries

Table 6.6: *Thiele, 2009 - Trial synopsis*

Trial details	Patients	Treatments	Outcomes
n=130 (65 vs. 65) **Follow-up duration:** 12 months **Study design:** Randomized controlled trial Parallel groups Open Confirmatory trial at risk of bias Germany, single center	Isolated LAD disease **Inclusion criteria:** age >18 years; isolated proximal LAD stenosis >50% (between origin of left circumflex artery and first septal perforator); symptomatic; presence of myocardial ischemia **Exclusion criteria:** acute coronary syndrome; additional valvular heart disease requiring surgical intervention; previous interventional or surgical treatment for coronary artery disease or valvular heart disease; severe peripheral vascular disease; significant carotid disease needing treatment; end-stage renal disease on hemodialysis; overt congestive heart failure; upper gastrointestinal bleeding <4 weeks; contraindication to antiplatelet therapy; diseases with limited life expectancy; extreme obesity; total occlusions; involvement of left main trunk; stenosis of first diagonal branch; intramyocardial	**Studied treatment:** sirolimus-eluting stent **Control treatment:** MIDCAB surgery **Concomittant treat.:**fro PCI: aspirin (at least 100 mg/day, subsequently 100 mg/day indefinitely) and clopidogrel (600 mg orally, followed by 75 mg/day for at least 12 months); during the procedure heparin (60 U/kg body weight);for surgery : aspirin 100 mg/day indefinitely	

Reference

Thiele H, Neumann-Schniedewind P, Jacobs S, Boudriot E, Walther T, Mohr FW, Schuler G, Falk V. Randomized comparison of minimally invasive direct coronary artery bypass surgery versus sirolimus-eluting stenting in isolated proximal left anterior descending coronary artery stenosis. J Am Coll Cardiol 2009 Jun 23;53:2324-31 [PMID=19539141]

7 Detailed results for stent

7.1 Available trials

A total of 5 RCTs which randomized 596 patients were identified: it compared stent with E-ACAB and 4 trials compared stent with MIDCAB.
The average study size was 119 patients (range 53 to 220). The first study was published in 2000, and the last study was published in 2002.
All trials were open-label in design. All included studies were reported in English language. We did not found any unpublished trial.
6 months MI data was reported in 4 trials; 4 trials reported data on 6 months death; 3 trials reported data on 6 months events; 2 trials reported data on long term death; 2 trials reported data on ; 2 trials reported data on long term cardiovascular events; 1 trials reported data on 1 year death from any cause; and 1 trials reported data on 1 year event.
Following tables 7.1 (page 48), 7.2 (page 48), 7.4 (page 50), and 7.3 (page 49) summarized the main characteristics of the trials including in this systematic review of randomized trials of stent.

Table 7.1: *Treatment description - PCI - stent*

Trial	Studied treatment	Control treatment
Stent versus E-ACAB		
Cisowski (0)	Tristar, Tera, Penta (Guidant) (Cordis)	endoscopic atraumatic coronary artery bypass grafting
Stent versus MIDCAB		
Diegeler (2002) [1, 2]	Various stents	minimally invasive direct coronary artery bypass (off-pump proceedure)
Drenth (2002) [3, 4, 5]	Stent type not reported	minimally invasive direct coronary artery bypass (off-pump proceedure
Grip (2001) [6]	Stent type not reported	minimally invasive direct coronary artery bypass (off-pump proceedure)
SIMA (2000) [7]	Any CE marked, but Palmaz-Schatz recommended	Conventional CABG or minimally invasive direct coronary artery bypass (off-pump proceedure) (10% of surgical procedures

Table 7.2: *Descriptions of participants - PCI - stent*

Trial	Patients
Stent versus E-ACAB	
Cisowski (0)	Single vessel disease ACC/AHA A or B lesion in proximal LAD Angina CCS II or higher Lesion diameter 3 mm orgreater/length 20mm or greater

continued...

Trial	Patients
Stent versus MIDCAB	
Diegeler (2002) [1, 2]	Single vessel disease Lesion =75% stenosis in proximal LAD or between origin of left circumflex and 1st septal branch
Drenth (2002) [3, 4, 5]	Single vessel disease Angina II Lesion (Grade B2 or C) of proximal LAD Suitable for CABG or stenting
Grip (2001) [6]	Single vessel disease engaging LAD Stable or unstable angina
SIMA (2000) [7]	Single vessel disease Symptomatic or silent ischaemia 1 LAD lesion Ejection fraction >45% Vessel >3.0mm

Table 7.3: *Design and methodological quality of trials - PCI - stent*

Trial	Design	Duration	Centre	Primary endpoint
Stent versus E-ACAB				
Cisowski, 0 n=100	parallel group open	2 years	Poland Single center	
Stent versus MIDCAB				
Diegeler, 2002 [1, 2] n=220	parallel group open confirmatory trial at risk of bias	5 years	Germany Multicentre	major adverse cardiac events
Drenth, 2002 [3, 4, 5] n=102	parallel group open confirmatory trial at risk of bias	6 months, 3 years	Netherlands Single centre	Major Adverse Cardiac and Cerebrovascular Events
Grip, 2001 [6] n=53	parallel group open		Sweden	
SIMA, 2000 [7] n=121	parallel group open	2.4 years	Europe Multicentre	death, myocardial infarction, revascularization

Table 7.4: *Trial characteristics - PCI - stent*

Trial	Age (mean, year)	Men (%)	Ejection fraction (%)	Extent of Disease	arterial grafts	stent (%)
Stent versus E-ACAB						
Cisowski, 0				single vessel disease	100%	100%
Stent versus MIDCAB						
Diegeler, 2002 [1, 2]				single vessel disease	100%	100%
Drenth, 2002 [3, 4, 5]				single vessel disease	100%	100%
Grip, 2001 [6]				a	NA	NA
SIMA, 2000 [7]				single vessel disease	98%	100%

7.2 Meta-analysis results

The results are detailed in table 7.5 (page 52). This table is followed by the Forest's plot corresponding to each endpoint.

Stent versus E-ACAB

The single study eligible for this comparison provided data on **6 months events**. The analysis detected a statistically significant difference in favor of E-ACAB in 6 months events, with a RR of 22.00 (95% CI 1.33 to 364.29, p=0.0309).
The single study eligible for this comparison provided data on **6 months death**. No statistically significant difference between the groups was found in 6 months death, with a RR of 1.00 (95% CI 0.02 to 49.42, p=1.0000).
The single study eligible for this comparison provided data on **6 months MI**. No statistically significant difference between the groups was found in 6 months MI, with a RR of 1.00 (95% CI 0.02 to 49.42, p=1.0000).

Stent versus MIDCAB

A total of 2 of the 4 studies eligible for this comparison provided data on **6 months events**. The analysis detected a statistically significant difference in favor of MIDCAB in 6 months events, with a RR of 2.06 (95% CI 1.27 to 3.33, p=0.0035). No heterogeneity was detected (p = 0.7664, I^2 = 0.00%).
Only one of the 4 studies eligible for this comparison provided data on **1 year event**. The analysis detected a statistically significant difference in favor of MIDCAB in 1 year event, with a RR of 3.00 (95% CI 1.04 to 8.68, p=0.0428).
A total of 2 of the 4 studies eligible for this comparison provided data on . The analysis detected a statistically significant difference in favor of MIDCAB in , with a RR of 3.24 (95% CI 1.61 to 6.54, p=0.0000). No heterogeneity was detected (p = 0.3771, I^2 = 0.00%).
A total of 3 of the 4 studies eligible for this comparison provided data on **6 months death**. When pooled together, there was no statistically significant difference between the groups in 6 months death, with a RR of 0.62 (95% CI 0.14 to 2.72, p=0.5279). No heterogeneity was detected (p = 0.7390, I^2 = 0.00%).
A total of 3 of the 4 studies eligible for this comparison provided data on **6 months MI**. When pooled together, there was no statistically significant difference between the groups in 6 months MI, with a RR of 1.21 (95% CI 0.32 to 4.54, p=0.7750). No heterogeneity was detected (p = 0.2578, I^2 = 0.26%).
A total of 2 of the 4 studies eligible for this comparison provided data on **long term cardiovascular events**. The analysis detected a statistically significant difference in favor of MIDCAB in long term cardiovascular events, with a RR of 3.24 (95% CI 1.61 to 6.54, p=0.0000). No heterogeneity was detected (p = 0.3771, I^2 = 0.00%).
Only one of the 4 studies eligible for this comparison provided data on **1 year death from any cause**. The analysis detected a statistically significant difference in favor of MIDCAB in 1 year death from any cause, with a RR of 3.00 (95% CI 1.04 to 8.68, p=0.0428).
A total of 2 of the 4 studies eligible for this comparison provided data on **long term death**. When pooled together, there was no statistically significant difference between the groups in long term death, with a RR of 0.10 (95% CI 0.00 to 8.53, p=0.3072). A random effect model was used because there was a substantial statistical heterogeneity detected between the studies (p = 0.0216, I^2 = 0.81%).

Table 7.5: *Results details - PCI - stent*

Comparison Endpoint	Effect	95% CI	p ass	p het	k	n
stent versus E-ACAB						
6 months events	RR=22.00	[1.33;364.29]	0.0309	1.0000 (I^2=0.00)	1	100
6 months death	RR=1.00	[0.02;49.42]	1.0000	1.0000 (I^2=0.00)	1	100
6 months MI	RR=1.00	[0.02;49.42]	1.0000	1.0000 (I^2=0.00)	1	100
stent versus MIDCAB						
6 months events	RR=2.06	[1.27;3.33]	0.0035	0.7664 (I^2=0.00)	2	318
1 year event	RR=3.00	[1.04;8.68]	0.0428	1.0000 (I^2=0.00)	1	102
	RR=3.24	[1.61;6.54]	0.0000	0.3771 (I^2=0.00)	2	223
6 months death	RR=0.62	[0.14;2.72]	0.5279	0.7390 (I^2=0.00)	3	371
6 months MI	RR=1.21	[0.32;4.54]	0.7750	0.2578 (I^2=0.26)	3	371
long term cardiovascular events	RR=3.24	[1.61;6.54]	0.0000	0.3771 (I^2=0.00)	2	223
1 year death from any cause	RR=3.00	[1.04;8.68]	0.0428	1.0000 (I^2=0.00)	1	102
long term death	RR=0.10	[0.00;8.53]	0.3072	0.0216 (I^2=0.81)	2	223

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 7.1: *Forest's plot for 6 months events*

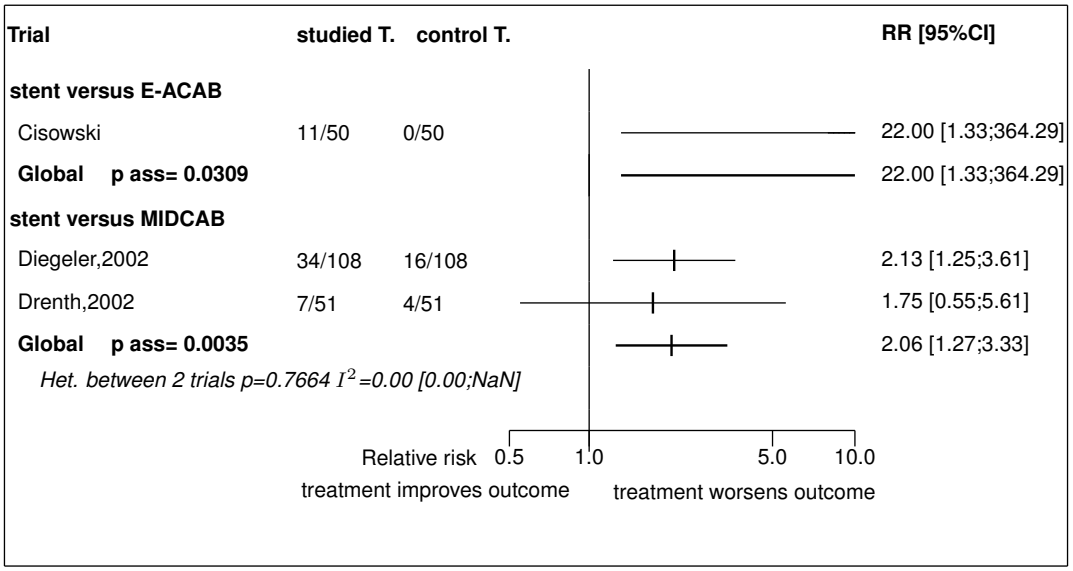


Figure 7.2: *Forest's plot for 1 year event*

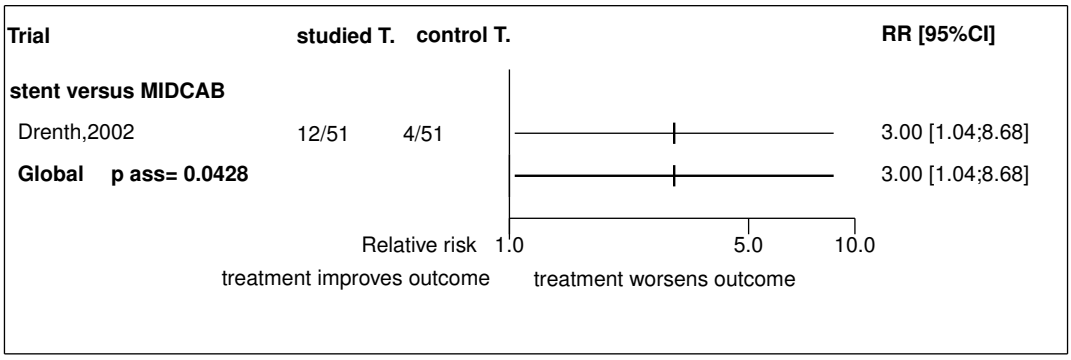


Figure 7.3: *Forest's plot for*

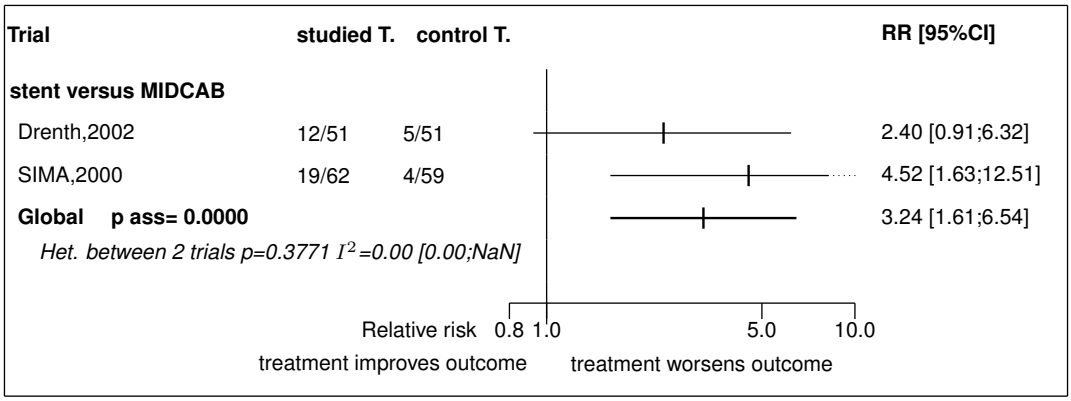


Figure 7.4: *Forest's plot for 6 months death*

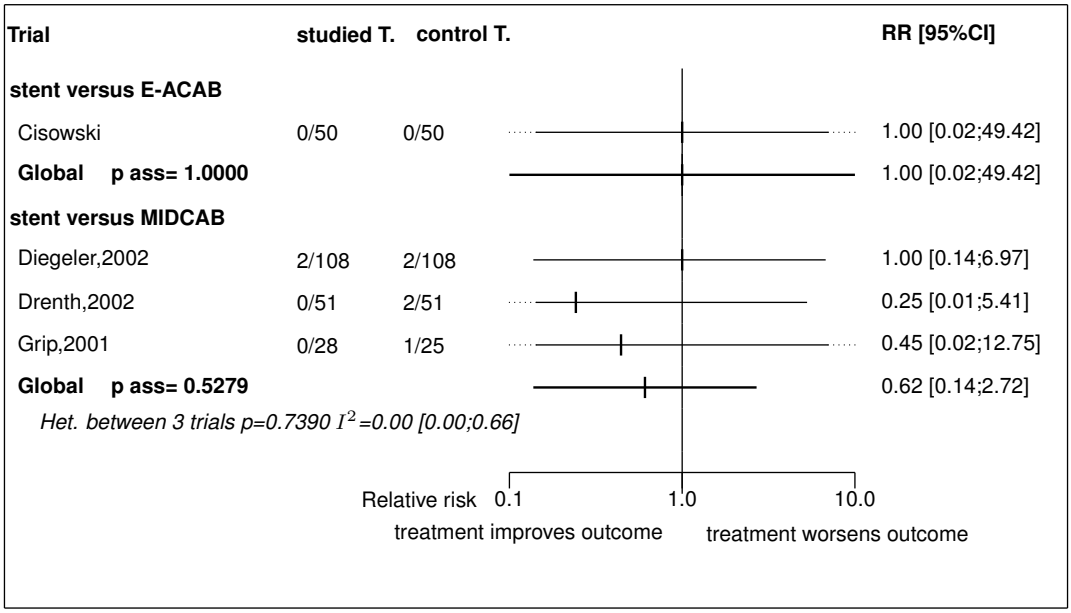


Figure 7.5: *Forest's plot for 6 months MI*

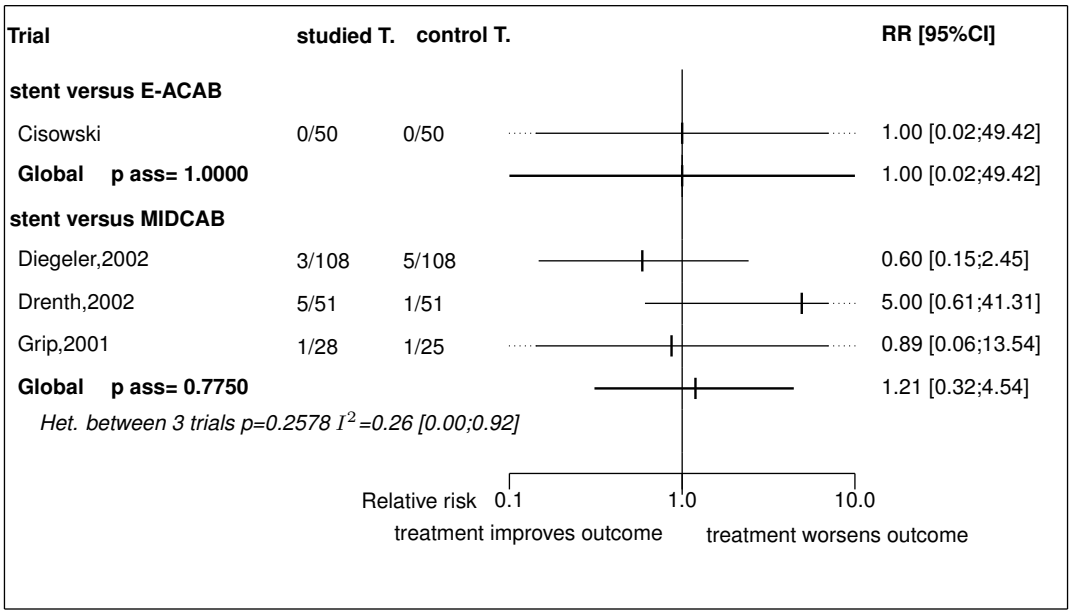


Figure 7.6: *Forest's plot for long term cardiovascular events*

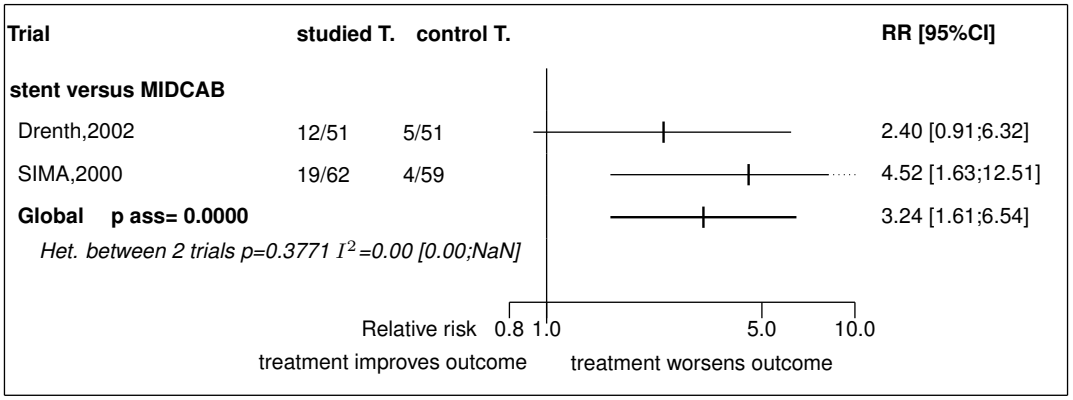


Figure 7.7: *Forest's plot for 1 year death from any cause*

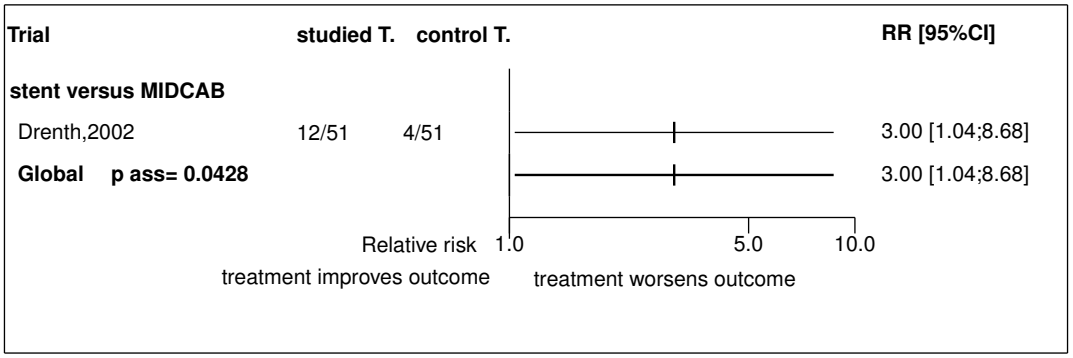
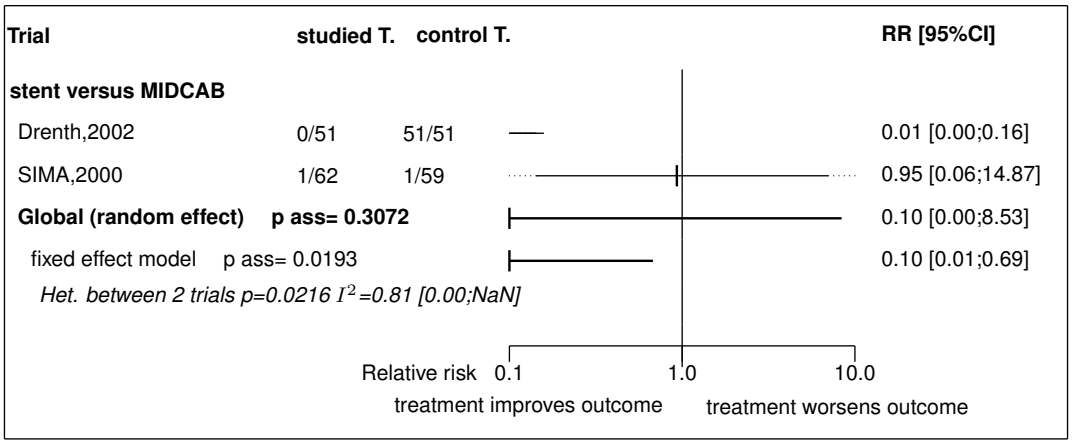


Figure 7.8: *Forest's plot for long term death*



References

[1] Diegeler A, Thiele H, Falk V, Hambrecht R, Spyrantis N, Sick P, Diederich KW, Mohr FW, Schuler G. Comparison of stenting with minimally invasive bypass surgery for stenosis of the left anterior descending coronary artery. N Engl J Med 2002;347:561-6. [PMID=12192015]

[2] Diegeler A, Spyrantis N, Matin M, Falk V, Hambrecht R, Autschbach R, Mohr FW, Schuler G. The revival of surgical treatment for isolated proximal high grade LAD lesions by minimally invasive coronary artery bypass grafting. Eur J Cardiothorac Surg 2000;17:501-4. [PMID=10814909]

[3] Drenth DJ, Veeger NJ, Grandjean JG, Mariani MA, van Boven AJ, Boonstra PW. Isolated high-grade lesion of the proximal LAD: a stent or off-pump LIMA?. Eur J Cardiothorac Surg 2004;25:567-71. [PMID=15037273]

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[5] Drenth DJ, Winter JB, Veeger NJ, Monnink SH, van Boven AJ, Grandjean JG, Mariani MA, Boonstra PW. Minimally invasive coronary artery bypass grafting versus percutaneous transluminal coronary angioplasty with stenting in isolated high-grade stenosis of the proximal left anterior descending coronary artery: six months' angiographic and clinical follow-up of a prospective randomized study. J Thorac Cardiovasc Surg 2002;124:130-5. [PMID=12091818]

[6] Grip L, Wahrborg P, Odell A, Albertsson P, Berglin E, Brandrup-. Coronary artery bypass beating heart surgery withLIMA graft, versus coronary angioplasty with stent for patients withsingle left anterior descending artery - a pilot study. European HeartJournal 2001;22 (Suppl):597.

[7] Goy JJ, Kaufmann U, Goy-Eggenberger D, Garachemani A, Hurni M, Carrel T, Gaspardone A, Burnand B, Meier B, Versaci F, Tomai F, Bertel O, Pieper M, de Benedictis M, Eeckhout E. A prospective randomized trial comparing stenting to internal mammary artery grafting for proximal, isolated de novo left anterior coronary artery stenosis: the SIMA trial. Stenting vs Internal Mammary Artery. Mayo Clin Proc 2000;75:1116-23. [PMID=11075740]

7.3 Individual trial summaries

Table 7.6: *Cisowski, 0 - Trial synopsis*

Trial details	Patients	Treatments	Outcomes
n=100 (50 vs. 50) **Follow-up duration:** 2 years **Study design:** Randomized controlled trial parallel group Open Poland, Single center	Single vessel disease ACC/AHA A or B lesion in proximal LAD Angina CCS II or higher Lesion diameter 3 mm orgreater/length 20mm or greater	**Studied treatment:** Tristar, Tera, Penta (Guidant) (Cordis) **Control treatment:** endoscopic atraumatic coronary artery bypass grafting	
Reference			

Table 7.7: *Diegeler, 2002 - Trial synopsis*

Trial details	Patients	Treatments	Outcomes
n=220 (110 vs. 110) **Follow-up duration:** 5 years **Study design:** Randomized controlled trial parallel group Open Confirmatory trial at risk of bias Germany, Multicentre	Single vessel disease Lesion =75% stenosis in proximal LAD or between origin of left circumflex and 1st septal branch	**Studied treatment:** Various stents **Control treatment:** minimally invasive direct coronary artery bypass (off-pump proceedure)	6 months events RR=2.13 [1.25;3.61] 6 months death RR=1.00 [0.14;6.97] 6 months MI RR=0.60 [0.15;2.45]

References

Diegeler A, Thiele H, Falk V, Hambrecht R, Spyrantis N, Sick P, Diederich KW, Mohr FW, Schuler G. Comparison of stenting with minimally invasive bypass surgery for stenosis of the left anterior descending coronary artery. N Engl J Med 2002;347:561-6 [PMID=12192015]

Diegeler A, Spyrantis N, Matin M, Falk V, Hambrecht R, Autschbach R, Mohr FW, Schuler G. The revival of surgical treatment for isolated proximal high grade LAD lesions by minimally invasive coronary artery bypass grafting. Eur J Cardiothorac Surg 2000;17:501-4 [PMID=10814909]

Table 7.8: *Drenth, 2002 - Trial synopsis*

Trial details	Patients	Treatments	Outcomes
n=102 (51 vs. 51) **Follow-up duration:** 6 months, 3 years **Study design:** Randomized controlled trial parallel group Open Confirmatory trial at risk of bias Netherlands, Single centre	Single vessel disease Angina II Lesion (Grade B2 or C) of proximal LAD Suitable for CABG or stenting	**Studied treatment:** Stent type not reported **Control treatment:** minimally invasive direct coronary artery bypass (off-pump proceedure	6 months events RR=1.75 [0.55;5.61] 1 year event RR=3.00 [1.04;8.68] RR=2.40 [0.91;6.32] 6 months MI RR=5.00 [0.61;41.31] Long term cardiovascular events RR=2.40 [0.91;6.32] 1 year death from any cause RR=3.00 [1.04;8.68]

References

Drenth DJ, Veeger NJ, Grandjean JG, Mariani MA, van Boven AJ, Boonstra PW. Isolated high-grade lesion of the proximal LAD: a stent or off-pump LIMA?. Eur J Cardiothorac Surg 2004;25:567-71 [PMID=15037273]
Drenth DJ, Veeger NJ, Winter JB, Grandjean JG, Mariani MA, Boven van AJ, Boonstra PW. A prospective randomized trial comparing stenting with off-pump coronary surgery for high-grade stenosis in the proximal left anterior descending coronary artery: three-year follow-up. J Am Coll Cardiol 2002;40:1955-60 [PMID=12475455]
Drenth DJ, Winter JB, Veeger NJ, Monnink SH, van Boven AJ, Grandjean JG, Mariani MA, Boonstra PW. Minimally invasive coronary artery bypass grafting versus percutaneous transluminal coronary angioplasty with stenting in isolated high-grade stenosis of the proximal left anterior descending coronary artery: six months' angiographic and clinical follow-up of a prospective randomized study. J Thorac Cardiovasc Surg 2002;124:130-5 [PMID=12091818]

Table 7.9: *Grip, 2001 - Trial synopsis*

Trial details	Patients	Treatments	Outcomes
n=53 (28 vs. 25) **Follow-up duration:** **Study design:** Randomized controlled trial parallel group Open Sweden	Single vessel disease engaging LAD Stable or unstable angina	**Studied treatment:** Stent type not reported **Control treatment:** minimally invasive direct coronary artery bypass (off-pump proceedure)	6 months MI RR=0.89 [0.06;13.54]

Reference

Grip L, Wahrborg P, Odell A, Albertsson P, Berglin E, Brandrup-. Coronary artery bypass beating heart surgery withLIMA graft, versus coronary angioplasty with stent for patients withsingle left anterior descending artery - a pilot study. European HeartJournal 2001;22 (Suppl):597

Table 7.10: *SIMA, 2000 - Trial synopsis*

Trial details	Patients	Treatments	Outcomes
n=121 (62 vs. 59) **Follow-up duration:** 2.4 years **Study design:** Randomized controlled trial parallel group Open Europe, Multicentre	Single vessel disease Symptomatic or silent ischaemia 1 LAD lesion Ejection fraction >45% Vessel >3.0mm	**Studied treatment:** Any CE marked, but Palmaz-Schatz recommended **Control treatment:** Conventional CABG or minimally invasive direct coronary artery bypass (off-pump proceedure) (10% of surgical procedures	RR=4.52 [1.63;12.51] Long term cardiovascular events RR=4.52 [1.63;12.51]

Reference

Goy JJ, Kaufmann U, Goy-Eggenberger D, Garachemani A, Hurni M, Carrel T, Gaspardone A, Burnand B, Meier B, Versaci F, Tomai F, Bertel O, Pieper M, de Benedictis M, Eeckhout E. A prospective randomized trial comparing stenting to internal mammary artery grafting for proximal, isolated de novo left anterior coronary artery stenosis: the SIMA trial. Stenting vs Internal Mammary Artery. Mayo Clin Proc 2000;75:1116-23 [PMID=11075740]

8 Global meta-analysis: all PCI

8.1 Global meta-analysis: all PCI versus CABG

Table 8.1: *All PCIversus CABG*

Endpoint	Effect	95% CI	p ass	p het (I^2)	k	n
cardiac death or MI	RR=3.49	0.99;12.28	0.0518	0.7031 (0.00)	2	276
CABG	RR=10.67	2.03;56.04	0.0052	0.6060 (0.00)	2	276
all cause death	RR=2.29	0.42;12.54	0.3407	0.4383 (0.00)	2	276

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

8.2 Global meta-analysis: all PCI versus E-ACAB

Table 8.2: *All PCIversus E-ACAB*

Endpoint	Effect	95% CI	p ass	p het (I^2)	k	n
6 months events	RR=22.00	1.33;364.29	0.0309	1.0000 (0.00)	1	100
6 months death	RR=1.00	0.02;49.42	1.0000	1.0000 (0.00)	1	100
6 months MI	RR=1.00	0.02;49.42	1.0000	1.0000 (0.00)	1	100

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

8.3 Global meta-analysis: all PCI versus MIDCAB

Table 8.3: *All PCIversus MIDCAB*

Endpoint	Effect	95% CI	p ass	p het (I^2)	k	n
6 months events	RR=2.06	1.27;3.33	0.0035	0.7664 (0.00)	2	318
1 year event	RR=3.00	1.04;8.68	0.0428	1.0000 (0.00)	1	102
	RR=3.24	1.61;6.54	0.0000	0.3771 (0.00)	2	223
6 months death	RR=0.62	0.14;2.72	0.5279	0.7390 (0.00)	3	371
6 months MI	RR=1.21	0.32;4.54	0.7750	0.2578 (0.26)	3	371
long term cardiovascular events	RR=3.24	1.61;6.54	0.0000	0.3771 (0.00)	2	223

continued...

Endpoint	Effect	95% CI	p ass	p het	k	n
1 year death from any cause	RR=3.00	1.04;8.68	0.0428	1.0000 (0.00)	1	102
long term death	RR=0.10 [1]	0.00;8.53	0.3072	0.0216 (0.81) †	2	223

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 Ongoing studies

No ongoing trial was identified.

10 Excluded studies

No trial was excluded.

References

[1] with a random model ($\tau^2 = NaN$). The results with a fixed effect model was RRFE=0.10 95% CI 0.01;0.69