Myocardial revascularization for stable angina in multivessels disease

A systematic review and meta-analysis of randomized clinical trials

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This report should be referenced as follows:
TrialResults-center.org; Results of all major randomized clinical trials about Myocardial revascularization for stable angina in multivessels disease.

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0.1 Synthesis of the meta-analysis results

We found 22 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 21 trials (including 13,074 patients) were identified .
Among these comparisons, 9 trials are about balloon angioplasty,one about PCI,one about PCI with drug-eluting stents,5 about PCI with or without stent and 6 about stent.
No trial was excluded on grounds of potentially flawed methodology or incomplete presentation of results. One ongoing trial was identified.

Balloon angioplasty

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

Table 1: *Results summary - Balloon angioplasty*

Benefit	Harmful	No evidence
	Balloon angioplasty versus medical treatment	
		→ PTCA RR=0.83^{NS} [0.41;1.69] k=2 → cardiac death or MI RR=1.06^{NS} [0.72;1.54] k=2 → myocardial infarction (fatal and non fatal) RR=0.92^{NS} [0.16;5.23] H k=2 → cardiac death RR=0.85^{NS} [0.48;1.52] k=1 → CABG RR=1.06^{NS} [0.77;1.46] k=2 → non fatal MI RR=1.32^{NS} [0.83;2.11] k=2 → angina RR=0.89^{NS} [0.72;1.09] k=2 → all cause death RR=0.99^{NS} [0.69;1.42] k=2
	Balloon angioplasty versus CABG	
↑ CABG RR=16.04¶ [9.73;26.43] k=6	↑ angina (grade 2 or worse) in first year RR=1.56¶ [1.20;2.04] k=4	→ cardiac death or MI RR=0.96^{NS} [0.72;1.29] k=6 → angina RR=1.31^{NS} [0.90;1.93] k=2 → all cause death RR=1.12^{NS} [0.93;1.36] k=7

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

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

PCI

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

Table 2: *Results summary - PCI*

Benefit	Harmful	No evidence
	PCI 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 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

* 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 with or without stent

Results obtained with PCI with or without stent for all the endpoints with data in at least one trial are summarized table 4.

Table 4: *Results summary - PCI with or without stent*

Benefit	Harmful	No evidence
	PCI with or without stent versus medical treatment	
	↑ PTCA RR=1.87* [1.02;3.44] k=5 ↑ cardiac death or MI RR=1.79* [1.07;2.98] k=5	→ myocardial infarction (fatal and non fatal) RR=0.93^{NS} [0.24;3.64] k=1 → cardiac death RR=0.93^{NS} [0.57;1.52] k=5 → CABG RR=1.16^{NS} [0.40;3.34] k=5 → non fatal MI RR=0.87^{NS} [0.55;1.36] k=5 → all cause death RR=0.91^{NS} [0.56;1.47] k=5

* 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 CABG	
	↑ 1 year event RR=1.82¶ [1.42;2.34] k=3 ↑ RR=2.01¶ [1.63;2.47] k=1 ↑ 1 year revascularization RR=4.88¶ [3.62;6.58] k=3 ↑ 2 yr MACE RR=2.01¶ [1.60;2.51] k=1	→ long term cardiovascular events RR=1.13^{NS} [0.81;1.56] H k=4 → 1 year death from any cause RR=0.94^{NS} [0.32;2.75] H k=3 → 1 year MI RR=0.91^{NS} [0.46;1.83] k=2 → long term MI RR=0.92^{NS} [0.47;1.82] H k=2 → long term death RR=1.00^{NS} [0.66;1.50] k=4 → all cause death RR=1.49^{NS} [0.81;2.71] k=1

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

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

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 multivessels 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 stable angina in multivessels 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 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 All cause death, Cardiac death or MI, CABG, PTCA, Non fatal MI, cardiac death, Long term death, Angina (grade 2 or worse) in first year, Angina, long term cardiovascular events, 1 year death from any cause, myocardial infarction (fatal and non fatal), long term MI, 2 yr MACE, 1 year revascularization, 1 year MI, 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 22 randomized comparisons which enrolled 13074 patients were identified. In all, 9 randomized comparisons concerned balloon angioplasty , one PCI , one PCI with drug-eluting stents , 5 PCI with or without stent and 6 stent.
The detailed descriptions of trials and meta-analysis results is given in section 3 (page 30) for balloon angioplasty, in section 4 (page 51) for PCI, in section 5 (page 58) for PCI with drug-eluting stents, in section 6 (page 66) for PCI with or without stent and in section 7 (page 81) for stent.

The average study size was 594 patients (range 41 to 1900). The first study was published in 1992, 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 2.1 (page 15) 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 19) and in the following graphs.

2.2.1 Balloon angioplasty

No significant difference was found between **balloon angioplasty** and **medical treatment** in terms of PTCA (RR=0.83, 95% CI 0.41 to 1.69, p=0.6074, 2 trials), cardiac death or MI (RR=1.06, 95% CI 0.72 to 1.54, p=0.7745, 2 trials), myocardial infarction (fatal and non fatal) (RR=0.92, 95% CI 0.16 to 5.23, p=0.9288, 2 trials)with a random effect model in reason of a heterogeneity (Het. p=0.0372)(RR=0.85, 95% CI 0.48 to 1.52, p=0.5829, 1 trial), CABG (RR=1.06, 95% CI 0.77 to 1.46, p=0.7279, 2 trials), non fatal MI (RR=1.32, 95% CI 0.83 to 2.11, p=0.2443, 2 trials), angina (RR=0.89, 95% CI 0.72 to 1.09, p=0.2602, 2 trials)and all cause death (RR=0.99, 95% CI 0.69 to 1.42, p=0.9605, 2 trials).

Balloon angioplasty was superior to **CABG** in terms of CABG (RR=16.04, 95% CI 9.73 to 26.43, p=0.0000, 6 trials). But balloon angioplasty increased the risk of angina (grade 2 or worse) in first year (RR=1.56, 95% CI 1.20 to 2.04, p=0.0000, 4 trials). However, no significant difference was found on cardiac death or MI (RR=0.96, 95% CI 0.72 to 1.29, p=0.7937, 6 trials), angina (RR=1.31, 95% CI 0.90 to 1.93, p=0.1630, 2 trials)and all cause death (RR=1.12, 95% CI 0.93 to 1.36, p=0.2386, 7 trials).

2.2.2 PCI

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

2.2.3 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).

2.2.4 PCI with or without stent

PCI with or without stent was inferior to **medical treatment** in terms of PTCA (RR=1.87, 95% CI 1.02 to 3.44, p=0.0436, 5 trials)and cardiac death or MI (RR=1.79, 95% CI 1.07 to 2.98, p=0.0260, 5 trials). No significant difference was found on myocardial infarction (fatal and non fatal) (RR=0.93, 95% CI 0.24 to 3.64, p=0.9131, 1 trial), cardiac death (RR=0.93, 95% CI 0.57 to 1.52, p=0.7725, 5 trials), CABG (RR=1.16, 95% CI 0.40 to 3.34, p=0.7804, 5 trials), non fatal MI (RR=0.87, 95% CI 0.55 to 1.36, p=0.5344, 5 trials)and all cause death (RR=0.91, 95% CI 0.56 to 1.47, p=0.6947, 5 trials).

2.2.5 Stent

Stent was inferior to **CABG** in terms of 1 year event (RR=1.82, 95% CI 1.42 to 2.34, p=0.0000, 3 trials), (RR=2.01, 95% CI 1.63 to 2.47, p=0.0000, 1 trial), 1 year revascularization (RR=4.88, 95% CI 3.62 to 6.58, p=0.0000, 3 trials)and 2 yr MACE (RR=2.01, 95% CI 1.60 to 2.51, p=0.0000, 1 trial). No significant difference was found on long term cardiovascular events (RR=1.13, 95% CI 0.81 to 1.56, p=0.4791, 4 trials)with a random effect model in reason of a heterogeneity (Het. p=0.0418)(RR=0.94, 95% CI 0.32 to 2.75, p=0.9155, 3 trials)with a random effect model in reason of a heterogeneity (Het. p=0.0136)(RR=0.91, 95% CI 0.46 to 1.83, p=0.7944, 2 trials), long term MI (RR=0.92, 95% CI 0.47 to 1.82, p=0.8166, 2 trials)with a random effect model in reason of a heterogeneity (Het. p=0.0386)(RR=1.00, 95% CI 0.66 to 1.50, p=0.9849, 4 trials)and all cause death (RR=1.49, 95% CI 0.81 to 2.71, p=0.1977, 1 trial).

Table 2.1: *Main study characteristics - PCI*

Trial	Patients	Treatments	Trial design and method
Balloon angioplasty			
Balloon angioplasty versus medical treatment			
RITA 2, 1997 [1, 2] n = 504 vs. 514	angina leading to admission within 90days, previous Q wave MI, no previousPTCA, no left main stem disease	PTCA within 3 mo of the randomisation **versus** medical treatment	open parallel groups UK
ACME 2 (Folland), 1997 [3, 4] n = 51 vs. 50	stable angina, history of angina, MIwithin 3 months, exercise test with STdepression >3 mm, no previous PTCA; Stenosis >70% proximal two thirds,no main artery stenosis >50%, no 3vessel disease	PTCA **versus** medical therapy	open parallel groups
Balloon angioplasty versus CABG			
EAST, 1994 [5] n = 198 vs. 194	patients with multivessels coronary artery disease	transluminal coronary angioplasty **versus** coronary-artery bypass grafting	open USA
GABI, 1994 [6] n = 182 vs. 177	patients with symptomatic multivessel coronary disease	percutaneous transluminal coronary angioplasty **versus** coronary-artery bypass grafting	open 8 centres, Germany
BARI, 1996 [7] n = 915 vs. 914	patients with multivessel disease	PTCA **versus** CABG	open USA, Canada
RITA, 1993 [8] n = 510 vs. 501	patients with one, two, or three diseased coronary arteries	percutaneous transluminal coronary angioplasty **versus** coronary artery bypass surgery	open UK

continued...

Trial	Patients	Treatments	Trial design and method
ERACI, 1992 [9] n = 63 vs. 64	patients with multivessel disease and lesions suitable for either form of therapy	percutaneous transluminal coronary angioplasty **versus** coronary artery bypass grafting	open Argentina
Toulouse, 1992 n = 76 vs. 76	patients with multivessels coronary artery disease	PTCA **versus** CABG	open France
CABRI, 1995 [10, 11] n = 541 vs. 513	patients with symptomatic multivessel coronary disease	percutaneous transluminal coronary angioplasty **versus** coronary artery bypass grafting	open Europe
PCI			
PCI versus CABG			
AWESOME, 2001 [1, 2, 3, 4, 5, 6, 7, 8] n = 222 vs. 232	high-risk patients with medically refractory ischemia	percutaneous coronary intervention **versus** coronary artery bypass graft	open parallel groups 16 centres, US (Veterans Affairs Medical Centers)
PCI with drug-eluting stents			
PCI with drug-eluting stents versus CABG			
FREEDOM, 2012 [1] 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
PCI with or without stent			
PCI with or without stent versus medical treatment			
AVERT, 1995 [1] n = 177 vs. 164	angina or asymptomatic, MI orunstable angina but not within 14 days,no triple vessel disease	angioplasty **versus** atorvastatin at 80 mg per day	open parallel groups

continued...

Trial	Patients	Treatments	Trial design and method
Dakik, 1998 [2] n = 19 vs. 22	stable survivors of AMI	PTCA **versus** intensive medical therapy	open parallel groups
MASS II, 2007 [3, 4, 5] n = 205 vs. 203	patients with multivessel coronary artery disease with stable angina and preserved ventricular function	PCI **versus** medical therapy	open parallel groups
Hambrecht, 2004 [6] n = 50 vs. 51	male patients aged 70 years	PCI **versus** 12 months of exercise training (20 minutes of bicycle ergometry per day)	open parallel groups
Bech, 2001 [7] n = 90 vs. 91	patients with planned PTCA and no documented ischemia and with coronary pressurederived fractional flow reserve >0.75	PTCA **versus** deferral of PTCA	open parallel groups
Stent			
Stent versus CABG			
ARTS, 2001 [1, 2, 3, 4, 5] n = 600 vs. 605	multi vessel disease with 2 or more de novo lesion in different major arteries Total occlusion <1month	palmaz-Schatz Crown/Cross flex (Cordis) **versus** conventional CABG	open parallel group Primary endpoint: major adverse cardiac and cerebrovascular events at one year Multicentre, International
CARDia (PCI), 2008 [6] 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
ERACI II, 2003 [7, 8] n = 225 vs. 225	multi vessel disease Angina CSS III-IV; no angina but large area of heart at risk; unstable =1 vessel to be treated Lesion >3.0mm	gianturco Robin II (Cook) Primary device **versus** conventional CABG	open parallel group Multicentre, Argentinad

continued...

Trial	Patients	Treatments	Trial design and method
MASS II, 2007 [9, 10] n = 205 vs. 203	patients with multivessel coronary artery disease with stable angina and preserved ventricular function	PCI (73% stent) **versus** CABG	open parallel groups Primary endpoint: MACE single-center, South America
Myoprotect, 2004 [11] n = 23 vs. 21	patients with symptomatic main-stem and main-stem-equivalent lesions with substantially increased risk for bypass surgery	percutaneous transluminal coronary angioplasty/stent **versus** CABG	open parallel groups Primary endpoint: not defined single center, Europe
SOS, 2002 [12, 13, 14, 15, 16, 17] n = 488 vs. 500	multiple vessel disease Symptomatic 1 or more vessel suitable for stenting	stent **versus** CABG	open parallel group Primary endpoint: repeat revascularisation Multicentre, Canada, United Kingdom, Europe

Table 2.2: *Summary of all results for balloon angioplasty*

Endpoint	Effect	95% CI	p ass	p het (I^2)	k	n
balloon angioplasty versus medical treatment						
PTCA	RR=0.83	0.41;1.69	0.6074	0.0825 (0.67)	2	1119
cardiac death or MI	RR=1.06	0.72;1.54	0.7745	0.8822 (0.00)	2	1119
myocardial infarction (fatal and non fatal)	RR=0.92 [1]	0.16;5.23	0.9288	0.0372 (0.77) †	2	1119
cardiac death	RR=0.85	0.48;1.52	0.5829	1.0000 (0.00)	1	1018
CABG	RR=1.06	0.77;1.46	0.7279	0.3640 (0.00)	2	1119
non fatal MI	RR=1.32	0.83;2.11	0.2443	0.5403 (0.00)	2	1119
angina	RR=0.89	0.72;1.09	0.2602	0.1824 (0.44)	2	1119
all cause death	RR=0.99	0.69;1.42	0.9605	0.7543 (0.00)	2	1119
balloon angioplasty versus CABG						
cardiac death or MI	RR=0.96	0.72;1.29	0.7937	0.2365 (0.26)	6	3095
angina (grade 2 or worse) in first year	RR=1.56	1.20;2.04	0.0000	0.1159 (0.49)	4	2610
CABG	RR=16.04	9.73;26.43	0.0000	0.8372 (0.00)	6	3095
angina	RR=1.31	0.90;1.93	0.1630	0.1638 (0.48)	2	1349
all cause death	RR=1.12	0.93;1.36	0.2386	0.5119 (0.00)	7	4924

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 PCI*

Endpoint	Effect	95% CI	p ass	p het (I^2)	k	n
PCI 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 2.4: *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

continued...

[1] with a random model ($\tau^2 = NaN$). The results with a fixed effect model was RRFE=1.49 95% CI 0.81;2.74

Endpoint	Effect	95% CI	p ass	p het	k	n
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 2.5: *Summary of all results for PCI with or without stent*

Endpoint	Effect	95% CI	p ass	p het (I^2)	k	n
PCI with or without stent versus medical treatment						
PTCA	RR=1.87	1.02;3.44	0.0436	0.1782 (0.36)	5	1072
cardiac death or MI	RR=1.79	1.07;2.98	0.0260	0.9011 (0.00)	5	1072
myocardial infarction (fatal and non fatal)	RR=0.93	0.24;3.64	0.9131	1.0000 (0.00)	1	341
cardiac death	RR=0.93	0.57;1.52	0.7725	0.9914 (0.00)	5	1075
CABG	RR=1.16	0.40;3.34	0.7804	0.2173 (0.31)	5	1072
non fatal MI	RR=0.87	0.55;1.36	0.5344	0.4538 (0.00)	5	1072
all cause death	RR=0.91	0.56;1.47	0.6947	0.9700 (0.00)	5	1072

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 CABG						
1 year event	RR=1.82	1.42;2.34	0.0000	0.1740 (0.43)	3	2703
	RR=2.01	1.63;2.47	0.0000	1.0000 (1.00)	1	1205
1 year revascularization	RR=4.88	3.62;6.58	0.0000	0.6615 (0.00)	3	2703
long term cardiovascular events	RR=1.13 [2]	0.81;1.56	0.4791	0.0418 (0.63) †	4	3051
1 year death from any cause	RR=0.94 [3]	0.32;2.75	0.9155	0.0136 (0.77) †	3	2643
1 year MI	RR=0.91	0.46;1.83	0.7944	0.0501 (0.74)	2	2193
long term MI	RR=0.92 [4]	0.47;1.82	0.8166	0.0386 (0.77) †	2	2193
long term death	RR=1.00	0.66;1.50	0.9849	0.0507 (0.61)	4	3051
2 yr MACE	RR=2.01	1.60;2.51	0.0000	1.0000 (0.00)	1	1205

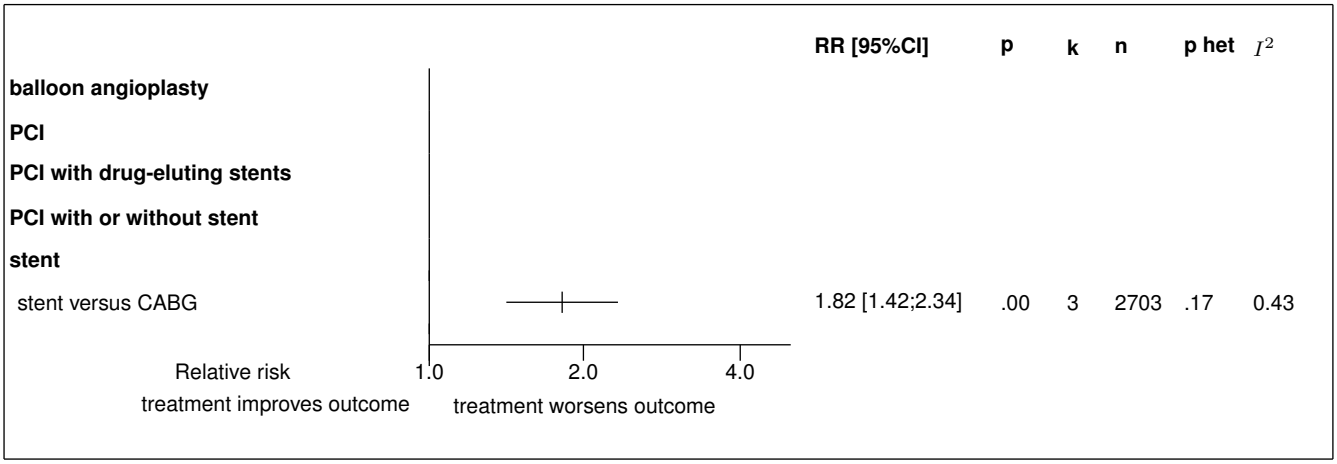
continued...

[2]with a random model ($\tau^2 = NaN$). The results with a fixed effect model was RRFE=1.04 95% CI 0.86;1.26
[3]with a random model ($\tau^2 = NaN$). The results with a fixed effect model was RRFE=0.86 95% CI 0.53;1.41
[4]with a random model ($\tau^2 = NaN$). The results with a fixed effect model was RRFE=0.93 95% CI 0.67;1.30

Endpoint	Effect	95% CI	p ass	p het	k	n
all cause death	RR=1.49	0.81;2.71	0.1977	1.0000 (0.00)	1	408

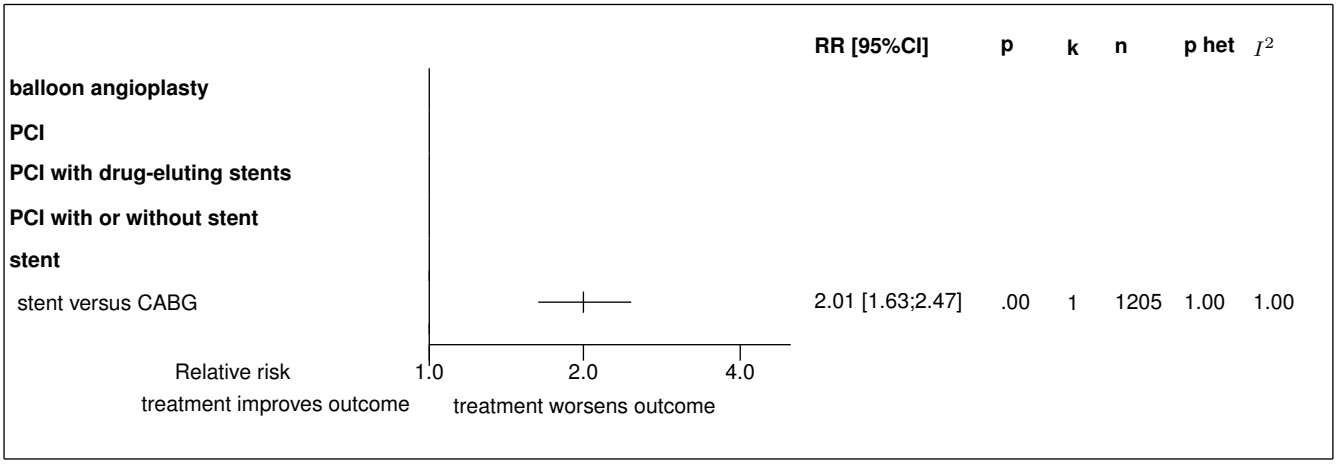
CI: confidence interval; p ass: p-value of association test; p het: p-value of the heterogeneity test; k: number of trials; n: total number of patients

Figure 2.1: *Forest's plot for 1 year event*



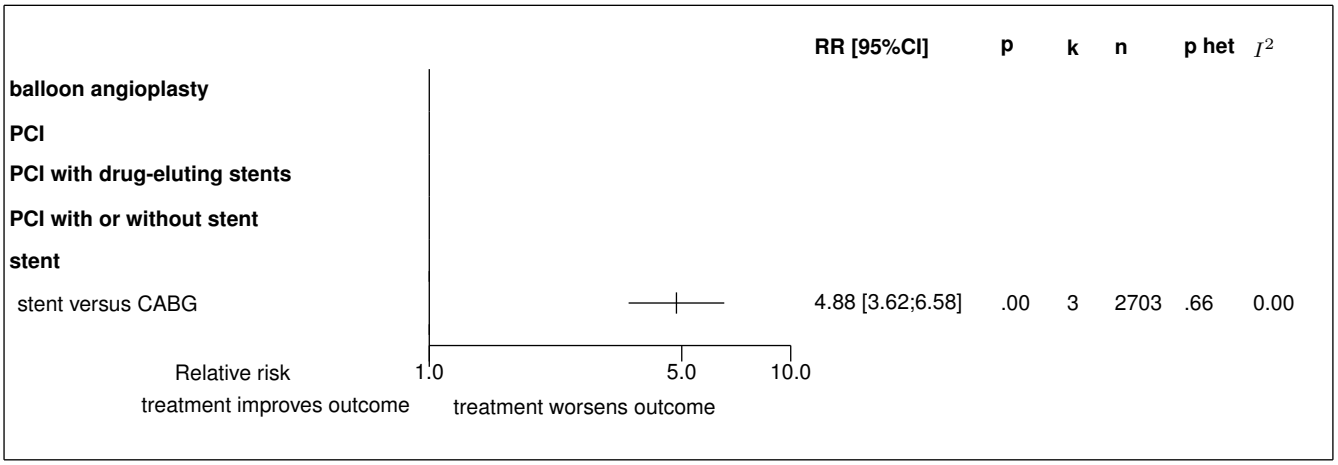
Results obtained with a fixed effect model except in case of heterogenity where a random model was used
RR: relative risk; 95% CI: 95% confidence interval; p: p-value of the association test; k: number of trials; n: total number of patients involving in the pooled trials; p het: p-value of the hetereogenity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

Figure 2.2: *Forest's plot for*



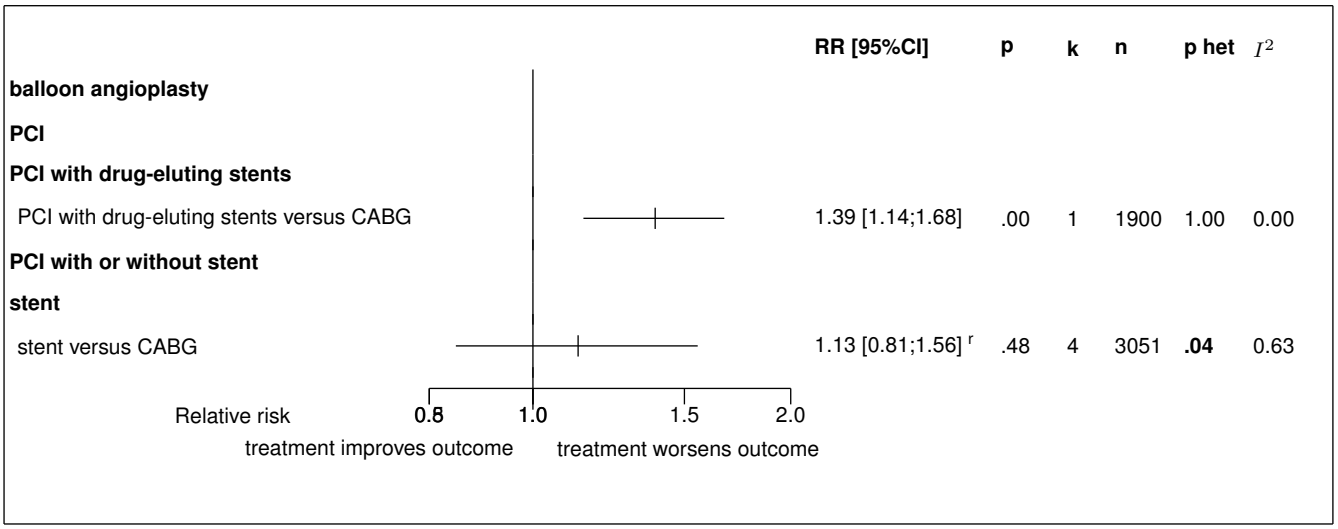
Results obtained with a fixed effect model except in case of heterogenity where a random model was used
RR: relative risk; 95% CI: 95% confidence interval; p: p-value of the association test; k: number of trials; n: total number of patients involving in the pooled trials; p het: p-value of the hetereogenity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

Figure 2.3: *Forest's plot for 1 year revascularization*



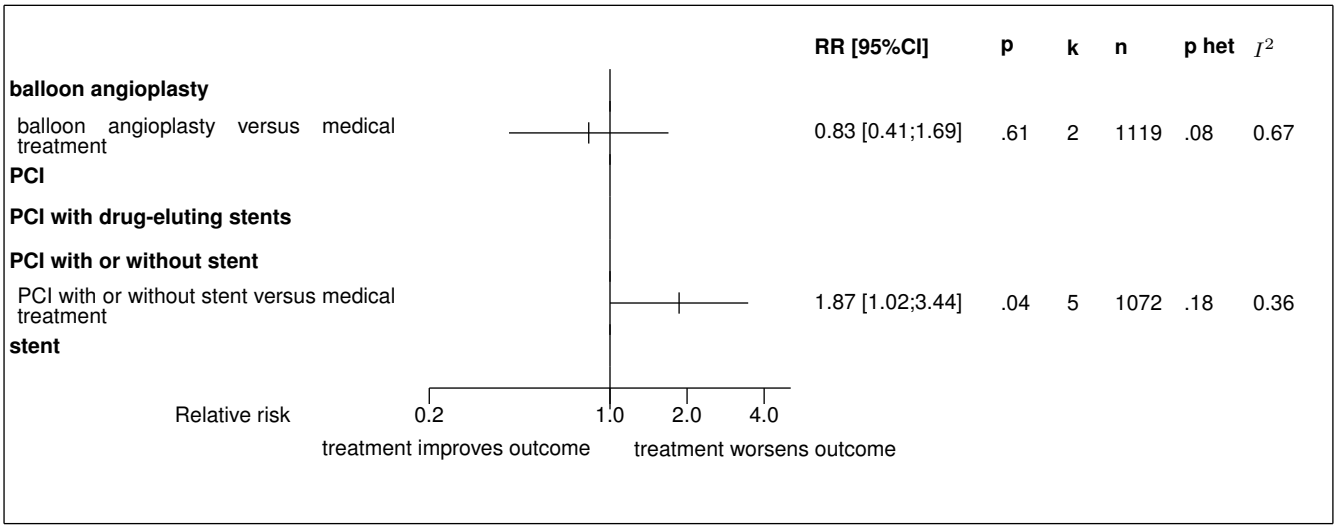
Results obtained with a fixed effect model except in case of heterogenity where a random model was used
RR: relative risk; 95% CI: 95% confidence interval; p: p-value of the association test; k: number of trials; n: total number of patients involving in the pooled trials; p het: p-value of the hetereogenity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

Figure 2.4: *Forest's plot for long term cardiovascular events*



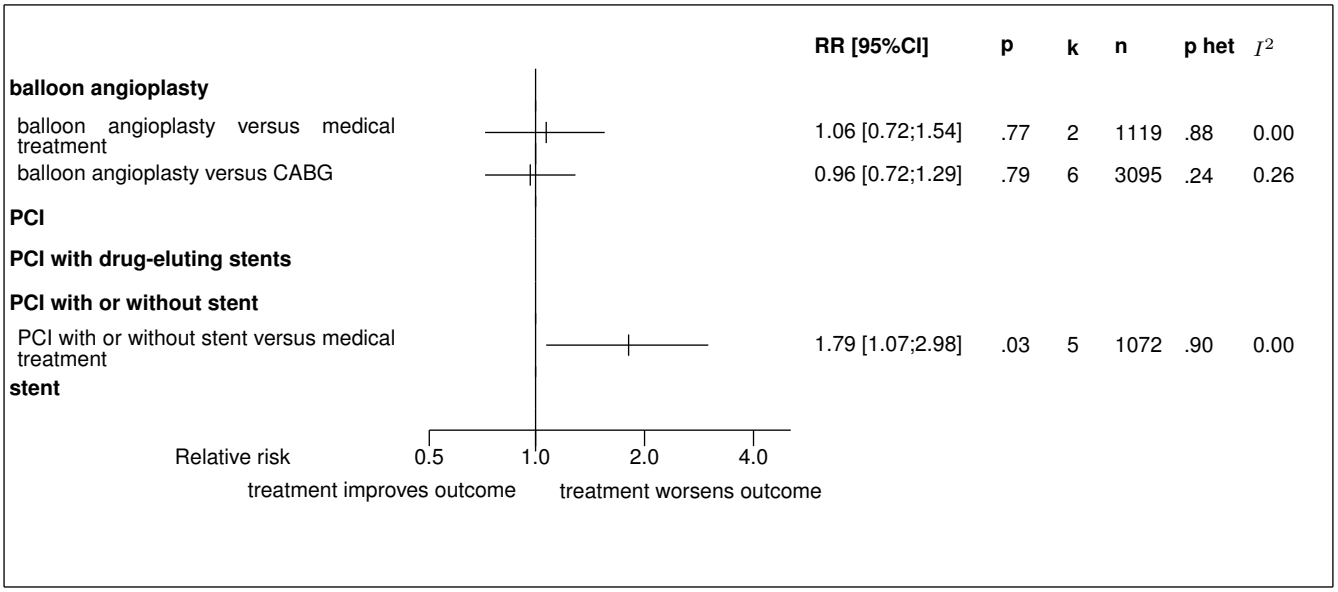
Results obtained with a fixed effect model except in case of heterogenity where a random model was used
RR: relative risk; 95% CI: 95% confidence interval; p: p-value of the association test; k: number of trials; n: total number of patients involving in the pooled trials; p het: p-value of the hetereogenity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

Figure 2.5: *Forest's plot for PTCA*



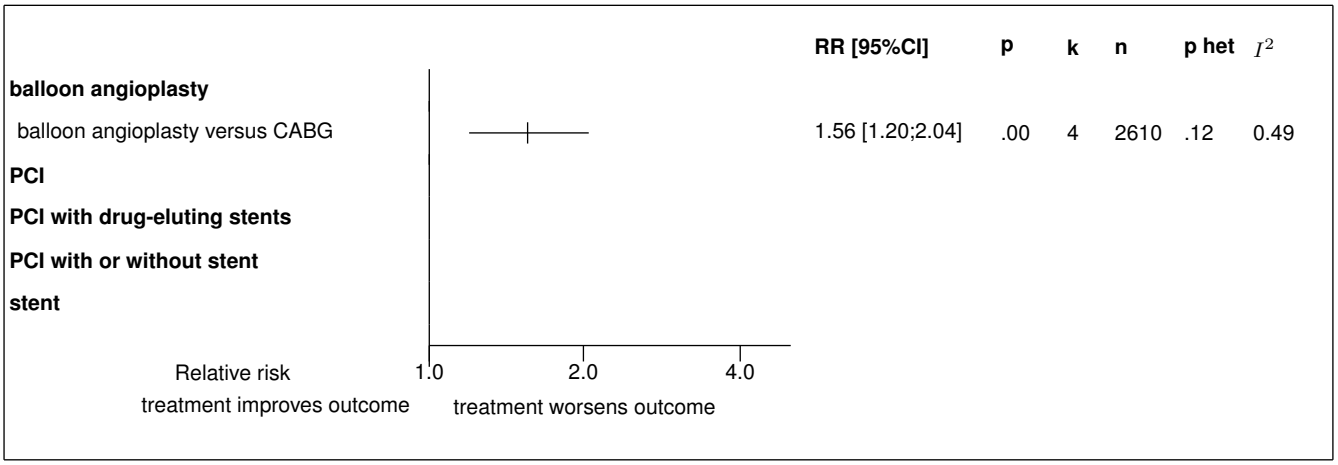
Results obtained with a fixed effect model except in case of heterogenity where a random model was used
RR: relative risk; 95% CI: 95% confidence interval; p: p-value of the association test; k: number of trials; n: total number of patients involving in the pooled trials; p het: p-value of the hetereogenity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

Figure 2.6: *Forest's plot for cardiac death or MI*



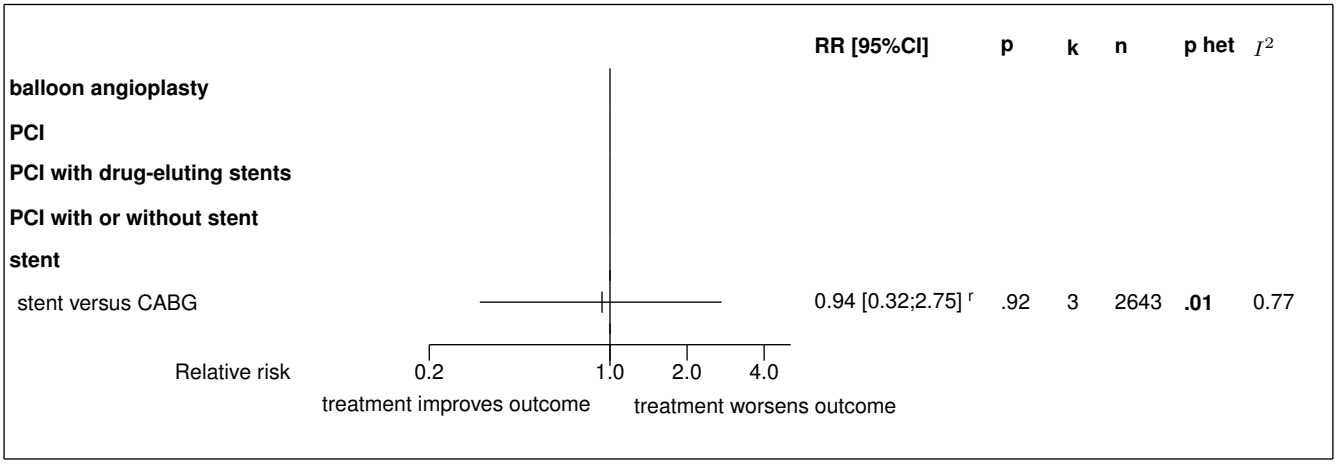
Results obtained with a fixed effect model except in case of heterogenity where a random model was used
RR: relative risk; 95% CI: 95% confidence interval; p: p-value of the association test; k: number of trials; n: total number of patients involving in the pooled trials; p het: p-value of the hetereogenity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

Figure 2.7: *Forest's plot for angina (grade 2 or worse) in first year*



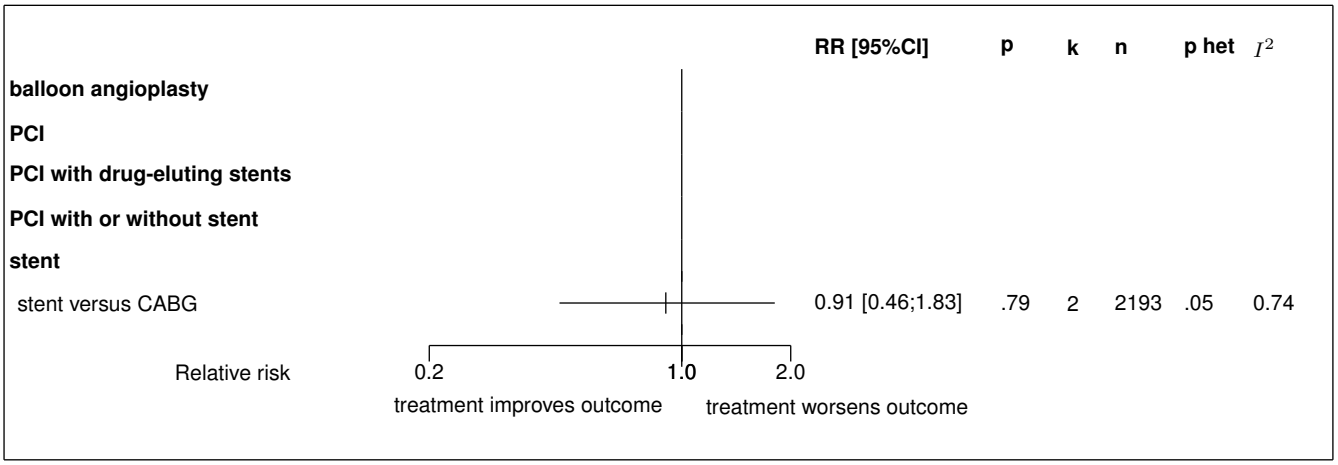
Results obtained with a fixed effect model except in case of heterogenity where a random model was used
RR: relative risk; 95% CI: 95% confidence interval; p: p-value of the association test; k: number of trials; n: total number of patients involving in the pooled trials; p het: p-value of the hetereogenity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

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



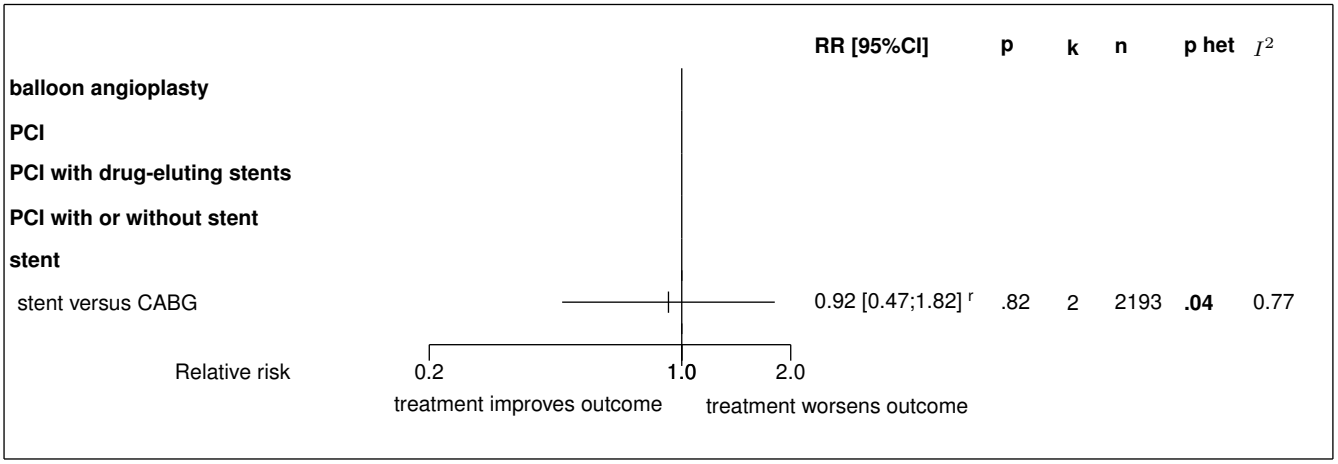
Results obtained with a fixed effect model except in case of heterogenity where a random model was used
RR: relative risk; 95% CI: 95% confidence interval; p: p-value of the association test; k: number of trials; n: total number of patients involving in the pooled trials; p het: p-value of the hetereogenity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

Figure 2.9: *Forest's plot for 1 year MI*



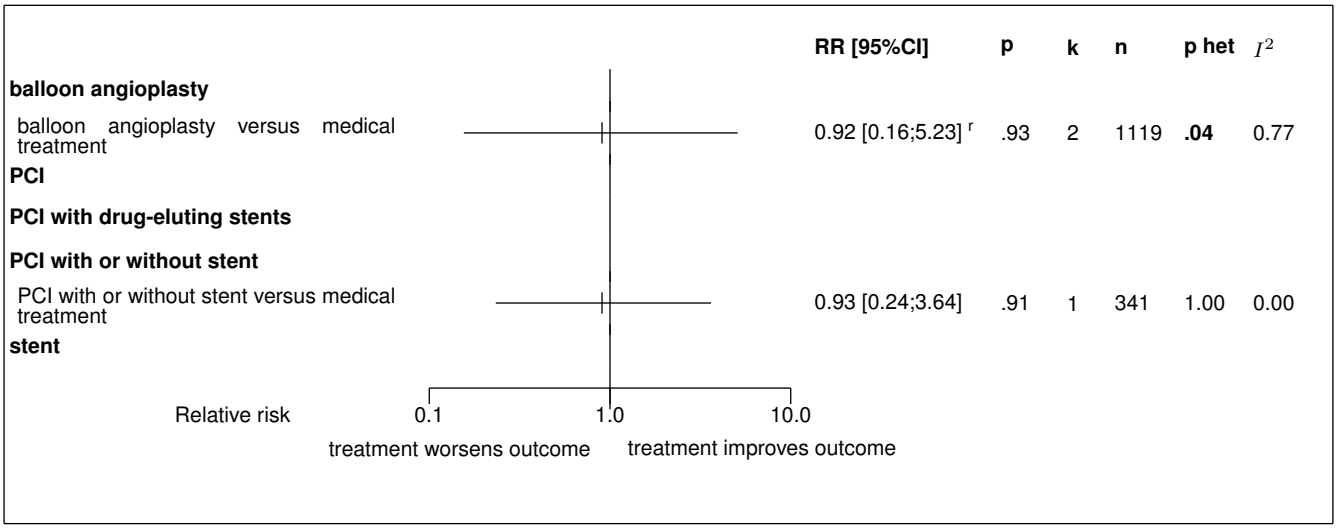
Results obtained with a fixed effect model except in case of heterogenity where a random model was used
RR: relative risk; 95% CI: 95% confidence interval; p: p-value of the association test; k: number of trials; n: total number of patients involving in the pooled trials; p het: p-value of the hetereogenity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

Figure 2.10: *Forest's plot for long term MI*



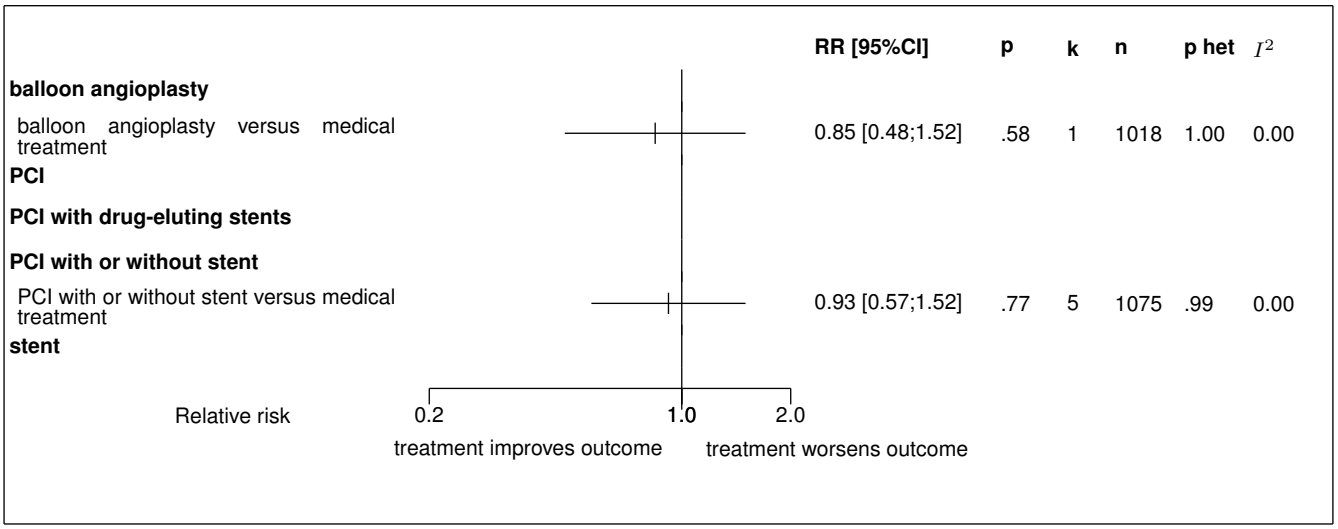
Results obtained with a fixed effect model except in case of heterogenity where a random model was used
RR: relative risk; 95% CI: 95% confidence interval; p: p-value of the association test; k: number of trials; n: total number of patients involving in the pooled trials; p het: p-value of the hetereogenity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

Figure 2.11: *Forest's plot for myocardial infarction (fatal and non fatal)*



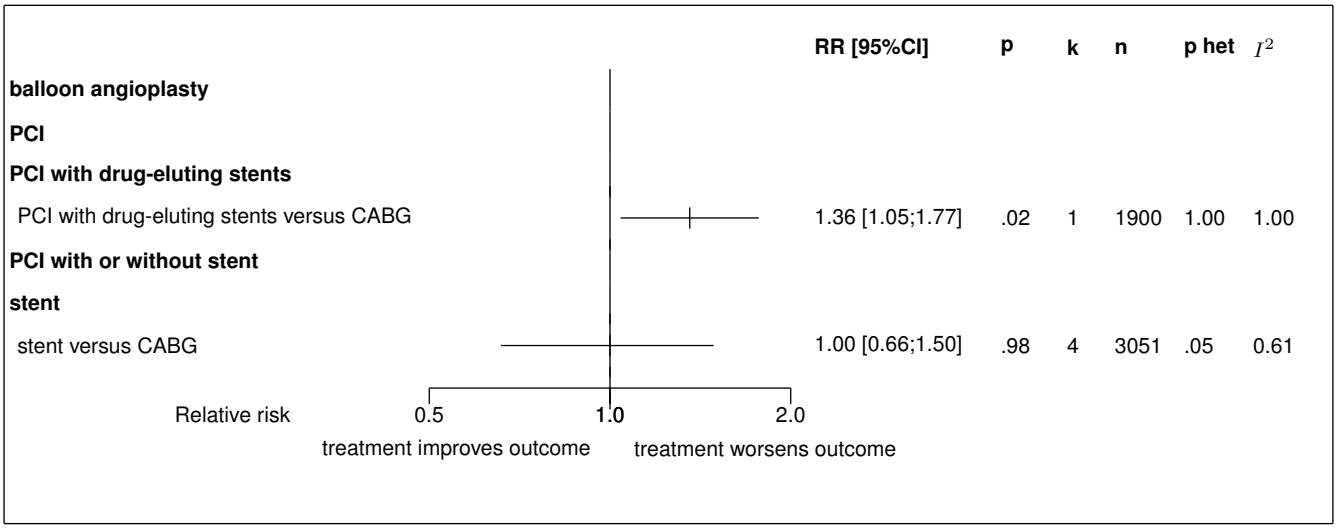
Results obtained with a fixed effect model except in case of heterogenity where a random model was used
RR: relative risk; 95% CI: 95% confidence interval; p: p-value of the association test; k: number of trials; n: total number of patients involving in the pooled trials; p het: p-value of the hetereogenity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

Figure 2.12: *Forest's plot for cardiac death*



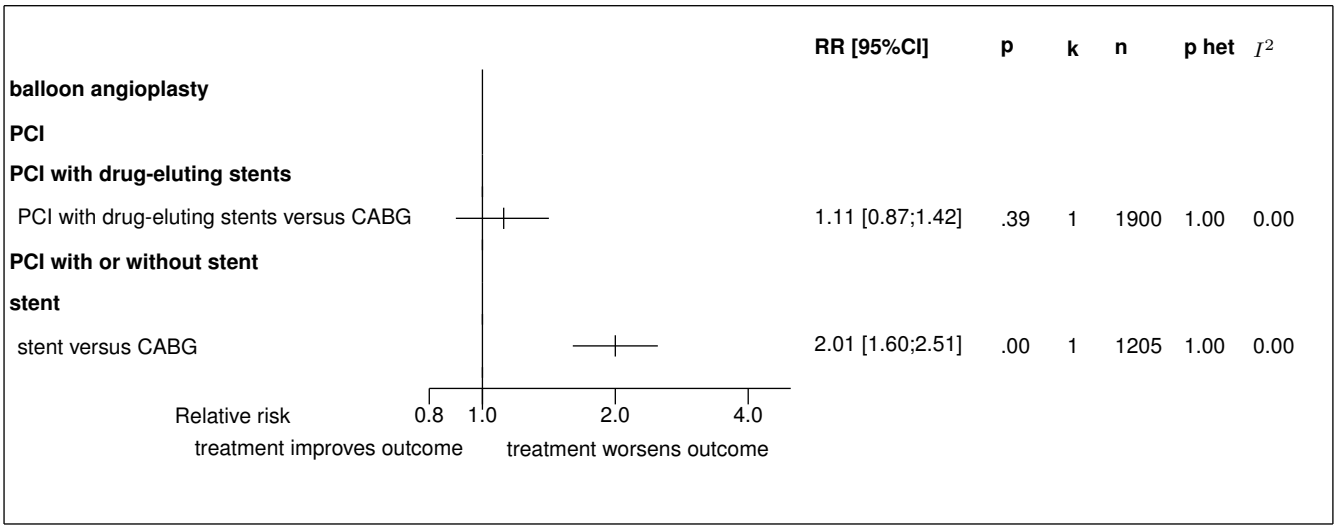
Results obtained with a fixed effect model except in case of heterogenity where a random model was used
RR: relative risk; 95% CI: 95% confidence interval; p: p-value of the association test; k: number of trials; n: total number of patients involving in the pooled trials; p het: p-value of the hetereogenity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

Figure 2.13: *Forest's plot for long term death*



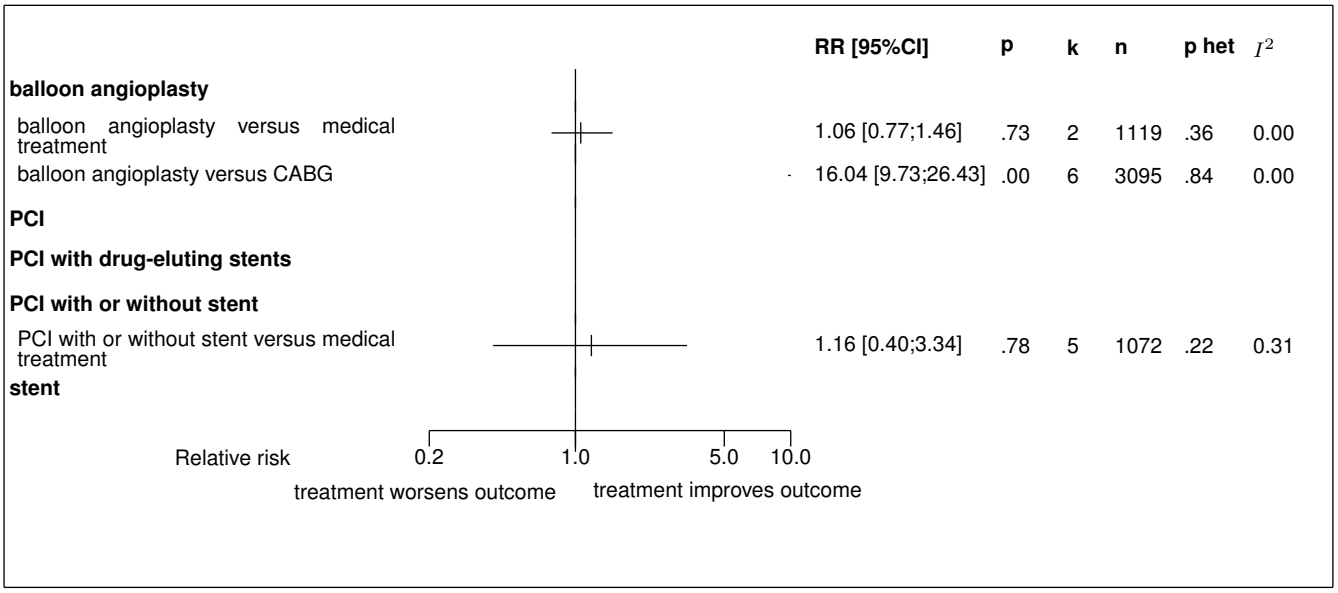
Results obtained with a fixed effect model except in case of heterogenity where a random model was used
RR: relative risk; 95% CI: 95% confidence interval; p: p-value of the association test; k: number of trials; n: total number of patients involving in the pooled trials; p het: p-value of the hetereogenity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

Figure 2.14: *Forest's plot for 2 yr MACE*



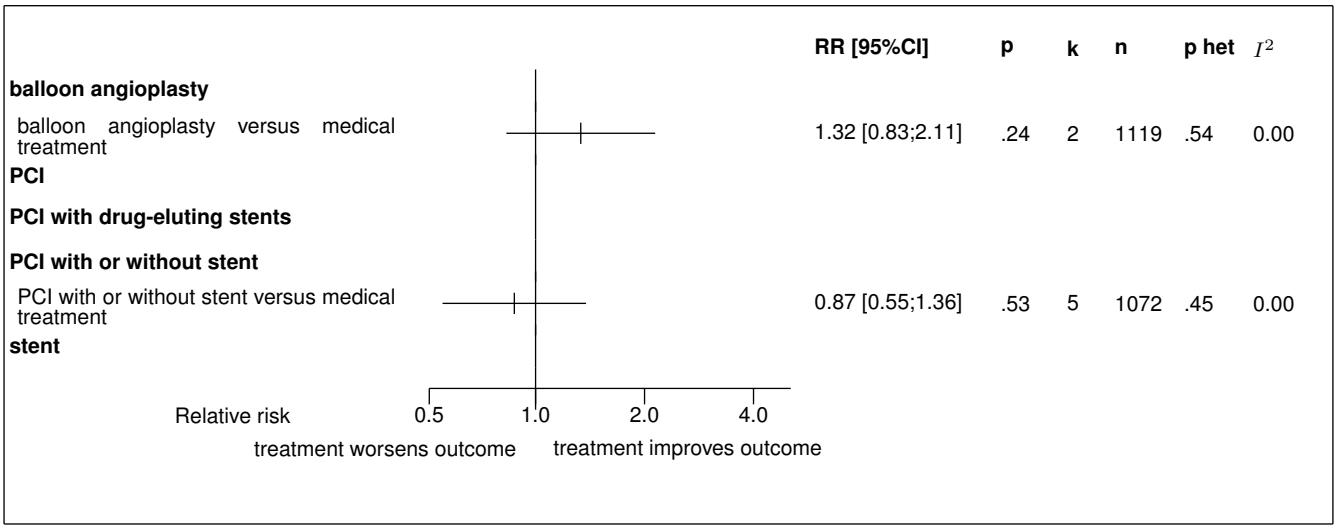
Results obtained with a fixed effect model except in case of heterogenity where a random model was used
RR: relative risk; 95% CI: 95% confidence interval; p: p-value of the association test; k: number of trials; n: total number of patients involving in the pooled trials; p het: p-value of the hetereogenity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

Figure 2.15: *Forest's plot for CABG*



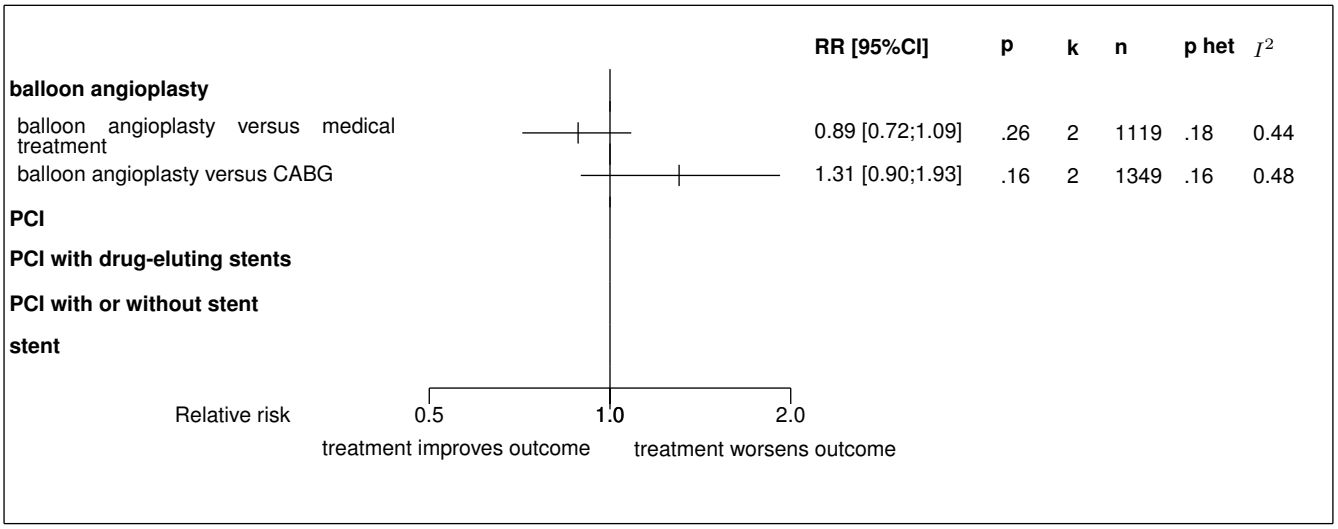
Results obtained with a fixed effect model except in case of heterogenity where a random model was used
RR: relative risk; 95% CI: 95% confidence interval; p: p-value of the association test; k: number of trials; n: total number of patients involving in the pooled trials; p het: p-value of the hetereogenity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

Figure 2.16: *Forest's plot for non fatal MI*



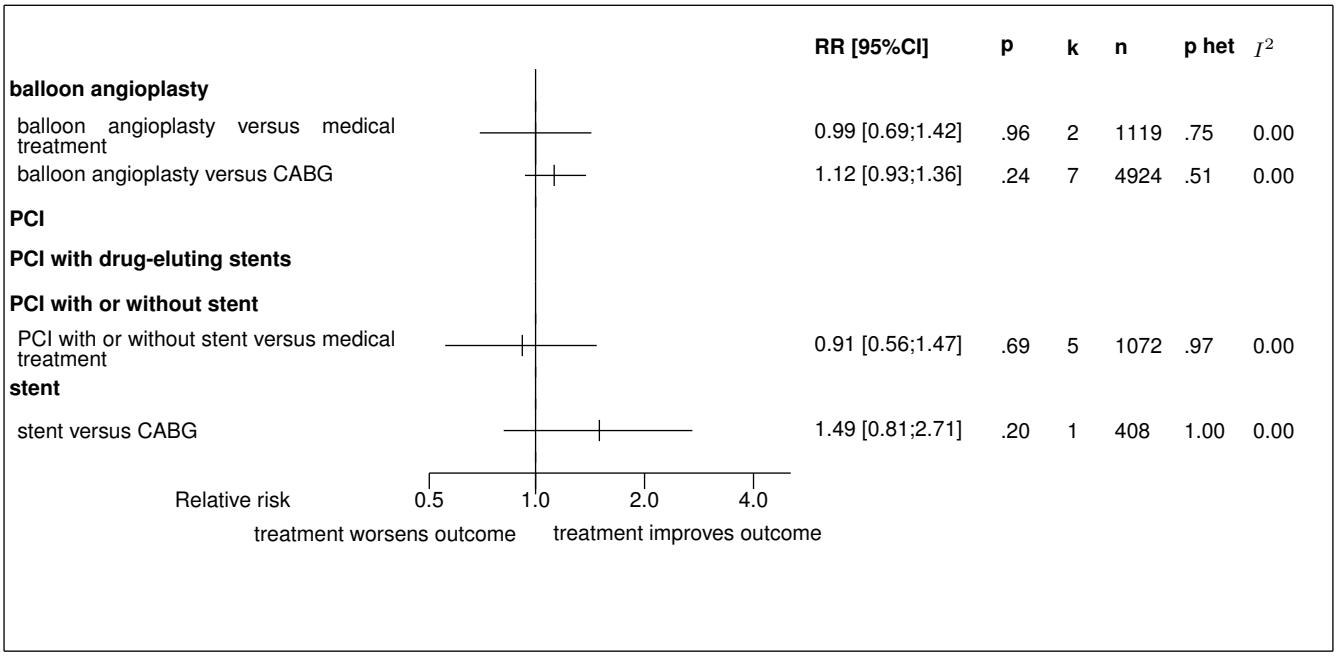
Results obtained with a fixed effect model except in case of heterogenity where a random model was used
RR: relative risk; 95% CI: 95% confidence interval; p: p-value of the association test; k: number of trials; n: total number of patients involving in the pooled trials; p het: p-value of the hetereogenity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

Figure 2.17: *Forest's plot for angina*



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 2.18: *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; ᶠ: random effect model used

3 Detailed results for balloon angioplasty

3.1 Available trials

A total of 9 RCTs which randomized 6043 patients were identified: 2 trials compared balloon angioplasty with medical treatment and 7 trials compared balloon angioplasty with CABG.
The average study size was 671 patients (range 101 to 1829). The first study was published in 1992, and the last study was published in 1997.
All trials were open-label in design. All included studies were reported in English language. We did not found any unpublished trial.
All cause death data was reported in 9 trials; 8 trials reported data on cardiac death or MI; 8 trials reported data on CABG; 4 trials reported data on angina (grade 2 or worse) in first year; 4 trials reported data on angina; 2 trials reported data on myocardial infarction (fatal and non fatal); 2 trials reported data on PTCA; 2 trials reported data on non fatal MI; and 1 trials reported data on cardiac death.
Following tables 3.1 (page 30), 3.2 (page 31), 3.4 (page 33), and 3.3 (page 31) summarized the main characteristics of the trials including in this systematic review of randomized trials of balloon angioplasty.

Table 3.1: *Treatment description - PCI - balloon angioplasty*

Trial	Studied treatment	Control treatment
Balloon angioplasty versus medical treatment		
RITA 2 (1997) [1, 2]	PTCA within 3 mo of the randomisation **Concomittant treatment:** aspirin	medical treatment
ACME 2 (Folland) (1997) [3, 4]	PTCA	medical therapy
Balloon angioplasty versus CABG		
EAST (1994) [5]	transluminal coronary angioplasty	coronary-artery bypass grafting
GABI (1994) [6]	Percutaneous transluminal coronary angioplasty	coronary-artery bypass grafting
BARI (1996) [7]	PTCA	CABG
RITA (1993) [8]	percutaneous transluminal coronary angioplasty	coronary artery bypass surgery
ERACI (1992) [9]	Percutaneous transluminal coronary angioplasty	coronary artery bypass grafting
Toulouse (1992)	PTCA	CABG
CABRI (1995) [10, 11]	percutaneous transluminal coronary angioplasty	coronary artery bypass grafting

continued...

Trial	Studied treatment	Control treatment

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

Trial	Patients	
Balloon angioplasty versus medical treatment		
RITA 2 (1997) [1, 2]	Angina leading to admission within 90days, previous Q wave MI, no previousPTCA, no left main stem disease	
	Inclusion criteria: patients with coronary artery disease proven arteriographically considered suitable for either treatment option	**Exclusion criteria:** <18y, early myocardial revascularisation needed, previous myocardiadial revascularisation, life-threatening disease
ACME 2 (Folland) (1997) [3, 4]	Stable angina, history of angina, MIwithin 3 months, exercise test with STdepression >3 mm, no previous PTCA; Stenosis >70% proximal two thirds,no main artery stenosis >50%, no 3vessel disease	
	Inclusion criteria: stable angina, history of angina, MIwithin 3 months, exercise test with STdepression >3 mm, no previous PTCAStenosis >70% proximal two thirds,no main artery stenosis >50%, no 3vessel disease	**Exclusion criteria:**
Balloon angioplasty versus CABG		
EAST (1994) [5]	Patients with multivessels coronary artery disease	
GABI (1994) [6]	Patients with symptomatic multivessel coronary disease	
BARI (1996) [7]	Patients with multivessel disease	
RITA (1993) [8]	Patients with one, two, or three diseased coronary arteries	
ERACI (1992) [9]	Patients with multivessel disease and lesions suitable for either form of therapy	
Toulouse (1992)	Patients with multivessels coronary artery disease	
CABRI (1995) [10, 11]	Patients with symptomatic multivessel coronary disease	

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

Trial	Design	Duration	Centre	Primary endpoint
Balloon angioplasty versus medical treatment				

continued...

Trial	Design	Duration	Centre	Primary end-point
RITA 2, 1997 [1, 2] n=1018	Parallel groups open confirmatory trial at risk of bias	7y inclusion period: 19921996	UK	
ACME 2 (Folland), 1997 [3, 4] n=101	Parallel groups open confirmatory trial at risk of bias	5y inclusion period: 19871990		
Balloon angioplasty versus CABG				
EAST, 1994 [5] n=392	open	3 y	USA	
GABI, 1994 [6] n=359	open	1 y	Germany 8 centres	
BARI, 1996 [7] n=1829	open	5.4 y	USA, Canada	
RITA, 1993 [8] n=1011	open	2.5 y (6.5y)	UK	
ERACI, 1992 [9] n=127	open	3.8 y	Argentina	
Toulouse, 1992 n=152	open	2.8 y	France	
CABRI, 1995 [10, 11] n=1054	open	1 y	Europe	

Table 3.4: *Trial characteristics - PCI - balloon angioplasty*

Trial
Balloon angioplasty versus medical treatment
RITA 2, 1997 [1, 2]
ACME 2 (Folland), 1997 [3, 4]
Balloon angioplasty versus CABG
EAST, 1994 [5]
GABI, 1994 [6]
BARI, 1996 [7]
RITA, 1993 [8]
ERACI, 1992 [9]
Toulouse, 1992
CABRI, 1995 [10, 11]

3.2 Meta-analysis results

The results are detailed in table 3.5 (page 35). This table is followed by the Forest's plot corresponding to each endpoint.

Balloon angioplasty versus medical treatment

All the 2 studies had extractable data about the number of participants with **PTCA**. When pooled together, there was no statistically significant difference between the groups in PTCA, with a RR of 0.83 (95% CI 0.41 to 1.69, p=0.6074). No heterogeneity was detected (p = 0.0825, I^2 = 0.67%).
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 1.06 (95% CI 0.72 to 1.54, p=0.7745). No heterogeneity was detected (p = 0.8822, I^2 = 0.00%).
All the 2 studies had extractable data about the number of participants with **myocardial infarction (fatal and non fatal)**. When pooled together, there was no statistically significant difference between the groups in myocardial infarction (fatal and non fatal), with a RR of 0.92 (95% CI 0.16 to 5.23, p=0.9288). A random effect model was used because there was a substantial statistical heterogeneity detected between the studies (p = 0.0372, I^2 = 0.77%).
Only one of the 2 studies eligible for this comparison provided data on **cardiac death**. No statistically significant difference between the groups was found in cardiac death, with a RR of 0.85 (95% CI 0.48 to 1.52, p=0.5829).
All the 2 studies had extractable data about the number of participants with **CABG**. When pooled together, there was no statistically significant difference between the groups in CABG, with a RR of 1.06 (95% CI 0.77 to 1.46, p=0.7279). No heterogeneity was detected (p = 0.3640, I^2 = 0.00%).
All the 2 studies had extractable data about the number of participants with **non fatal MI**. When pooled together, there was no statistically significant difference between the groups in non fatal MI, with a RR of 1.32 (95% CI 0.83 to 2.11, p=0.2443). No heterogeneity was detected (p = 0.5403, I^2 = 0.00%).
All the 2 studies had extractable data about the number of participants with **angina**. When pooled together, there was no statistically significant difference between the groups in angina, with a RR of 0.89 (95% CI 0.72 to 1.09, p=0.2602). No heterogeneity was detected (p = 0.1824, I^2 = 0.44%).
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 0.99 (95% CI 0.69 to 1.42, p=0.9605). No heterogeneity was detected (p = 0.7543, I^2 = 0.00%).

Balloon angioplasty versus CABG

A total of 6 of the 7 studies eligible for this comparison provided data on **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 0.96 (95% CI 0.72 to 1.29, p=0.7937). No heterogeneity was detected (p = 0.2365, I^2 = 0.26%).
A total of 4 of the 7 studies eligible for this comparison provided data on **angina (grade 2 or worse) in first year**. The analysis detected a statistically significant difference in favor of CABG in angina (grade 2 or worse) in first year, with a RR of 1.56 (95% CI 1.20 to 2.04, p=0.0000). No heterogeneity was detected (p = 0.1159, I^2 = 0.49%).
A total of 6 of the 7 studies eligible for this comparison provided data on **CABG**. The analysis detected a statistically significant difference in favor of balloon angioplasty in CABG, with a RR

of 16.04 (95% CI 9.73 to 26.43, p=0.0000). No heterogeneity was detected (p = 0.8372, I^2 = 0.00%).
A total of 2 of the 7 studies eligible for this comparison provided data on **angina**. When pooled together, there was no statistically significant difference between the groups in angina, with a RR of 1.31 (95% CI 0.90 to 1.93, p=0.1630). No heterogeneity was detected (p = 0.1638, I^2 = 0.48%).
All the 7 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 1.12 (95% CI 0.93 to 1.36, p=0.2386). No heterogeneity was detected (p = 0.5119, I^2 = 0.00%).

Table 3.5: *Results details - PCI - balloon angioplasty*

Comparison Endpoint	Effect	95% CI	p ass	p het	k	n
balloon angioplasty versus medical treatment						
PTCA	RR=0.83	[0.41;1.69]	0.6074	0.0825 (I^2=0.67)	2	1119
cardiac death or MI	RR=1.06	[0.72;1.54]	0.7745	0.8822 (I^2=0.00)	2	1119
myocardial infarction (fatal and non fatal)	RR=0.92	[0.16;5.23]	0.9288	0.0372 (I^2=0.77)	2	1119
cardiac death	RR=0.85	[0.48;1.52]	0.5829	1.0000 (I^2=0.00)	1	1018
CABG	RR=1.06	[0.77;1.46]	0.7279	0.3640 (I^2=0.00)	2	1119
non fatal MI	RR=1.32	[0.83;2.11]	0.2443	0.5403 (I^2=0.00)	2	1119
angina	RR=0.89	[0.72;1.09]	0.2602	0.1824 (I^2=0.44)	2	1119
all cause death	RR=0.99	[0.69;1.42]	0.9605	0.7543 (I^2=0.00)	2	1119
balloon angioplasty versus CABG						
cardiac death or MI	RR=0.96	[0.72;1.29]	0.7937	0.2365 (I^2=0.26)	6	3095
angina (grade 2 or worse) in first year	RR=1.56	[1.20;2.04]	0.0000	0.1159 (I^2=0.49)	4	2610
CABG	RR=16.04	[9.73;26.43]	0.0000	0.8372 (I^2=0.00)	6	3095
angina	RR=1.31	[0.90;1.93]	0.1630	0.1638 (I^2=0.48)	2	1349
all cause death	RR=1.12	[0.93;1.36]	0.2386	0.5119 (I^2=0.00)	7	4924

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 PTCA*

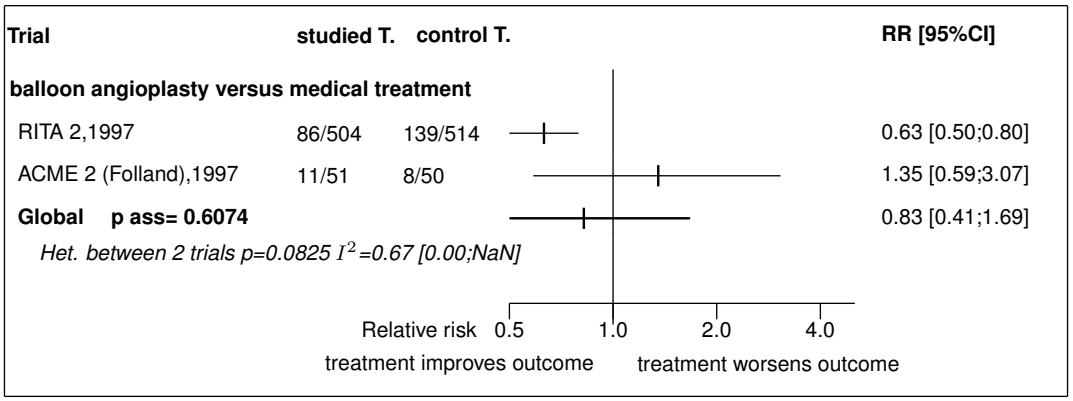


Figure 3.2: *Forest's plot for cardiac death or MI*

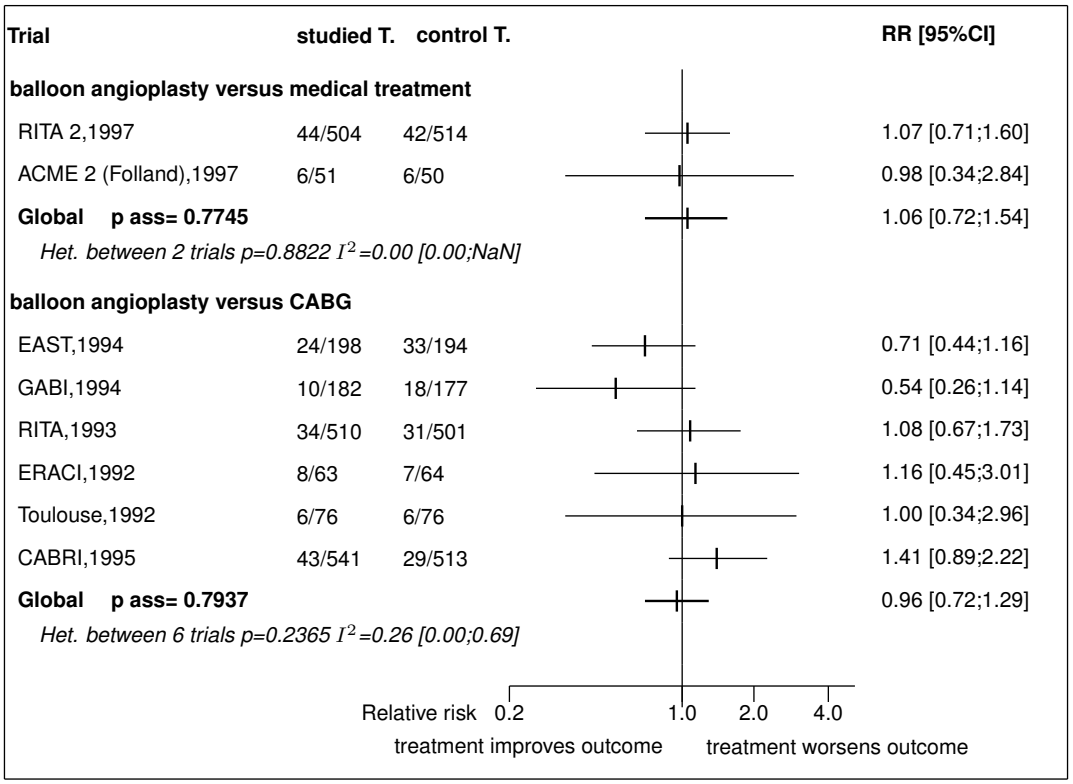


Figure 3.3: *Forest's plot for angina (grade 2 or worse) in first year*

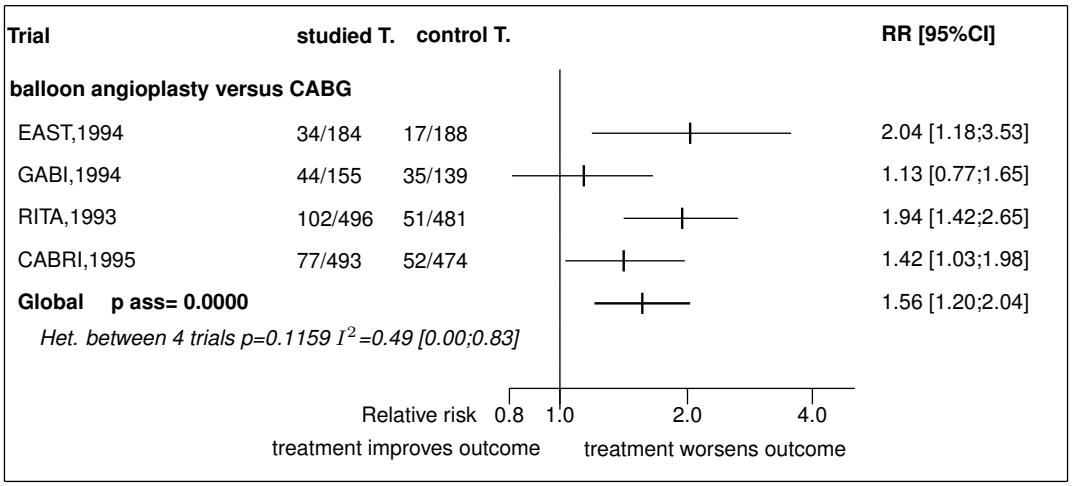


Figure 3.4: *Forest's plot for myocardial infarction (fatal and non fatal)*

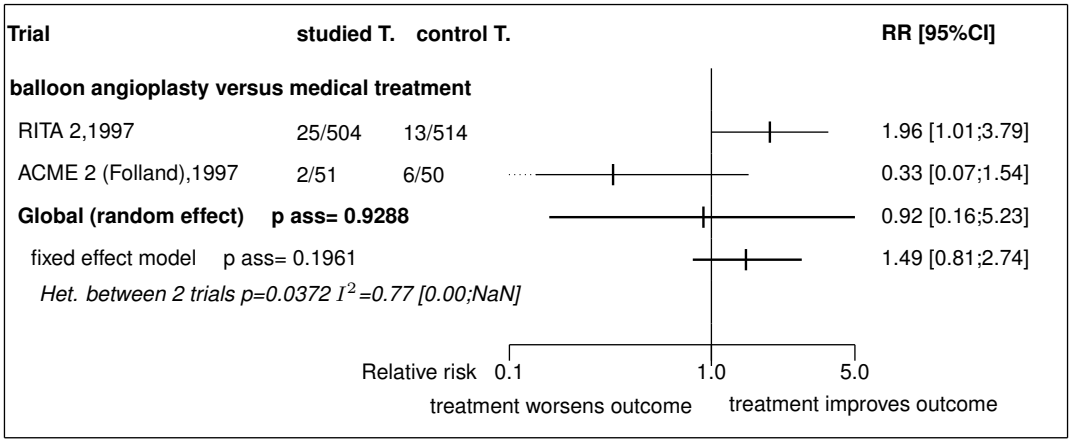


Figure 3.5: *Forest's plot for cardiac death*

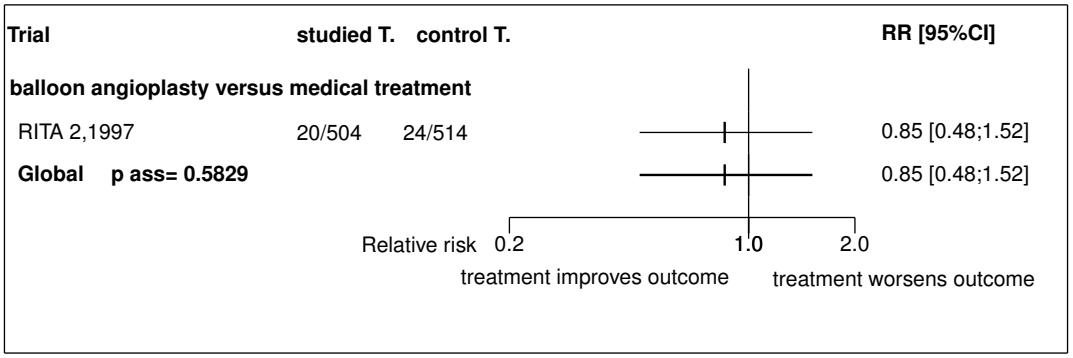


Figure 3.6: *Forest's plot for CABG*

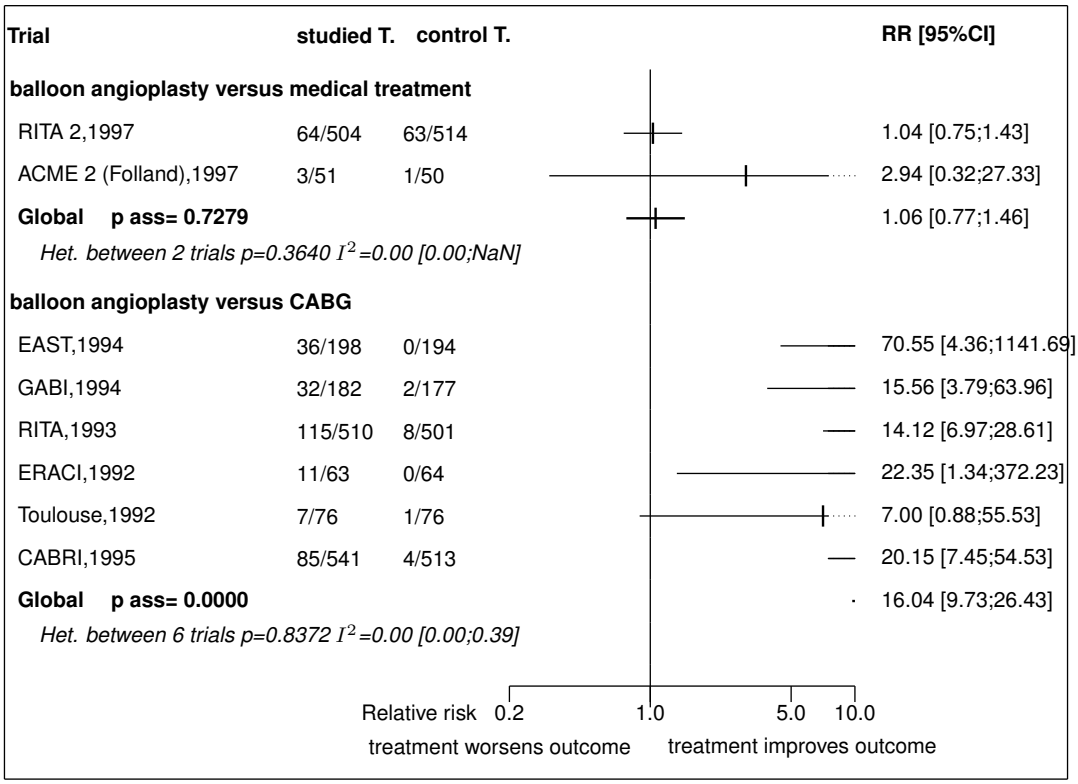


Figure 3.7: *Forest's plot for non fatal MI*

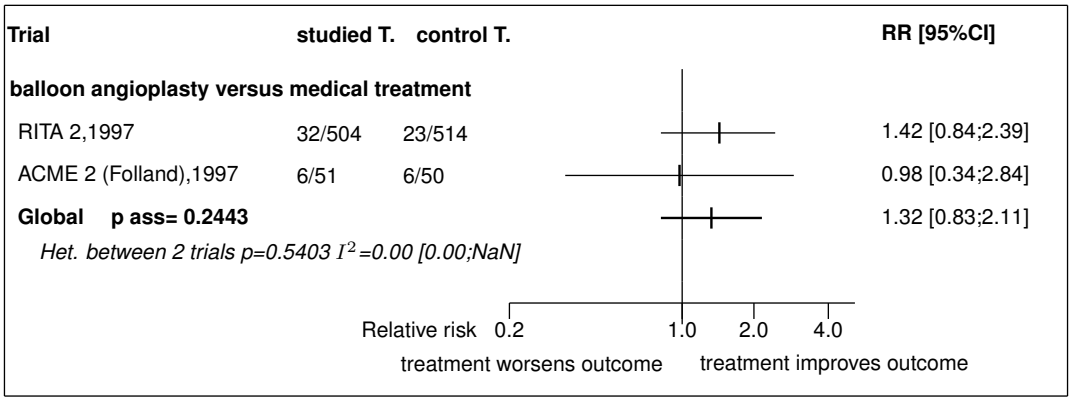


Figure 3.8: *Forest's plot for angina*

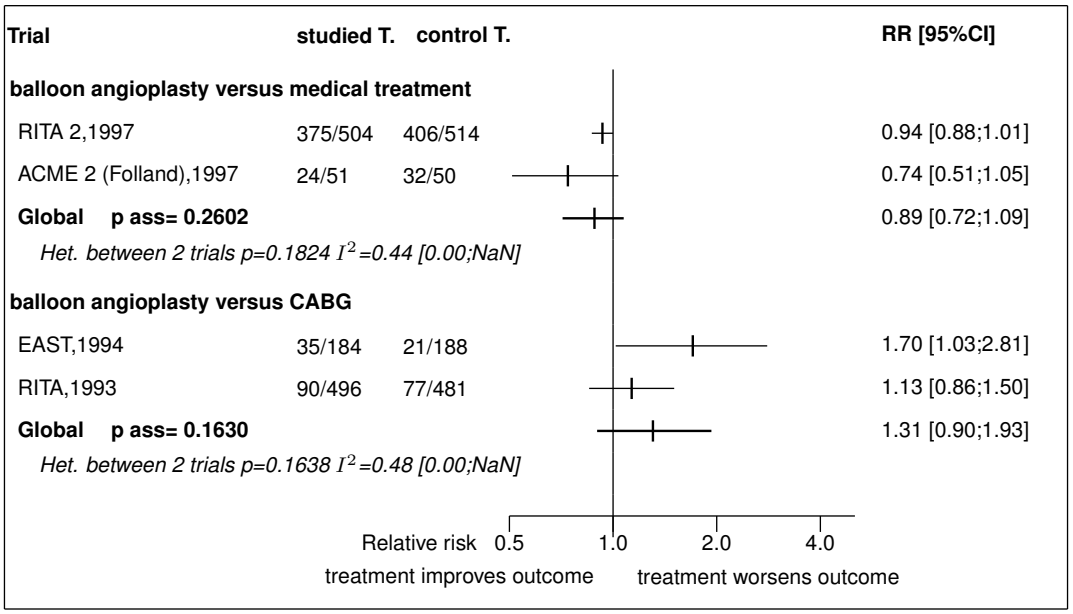
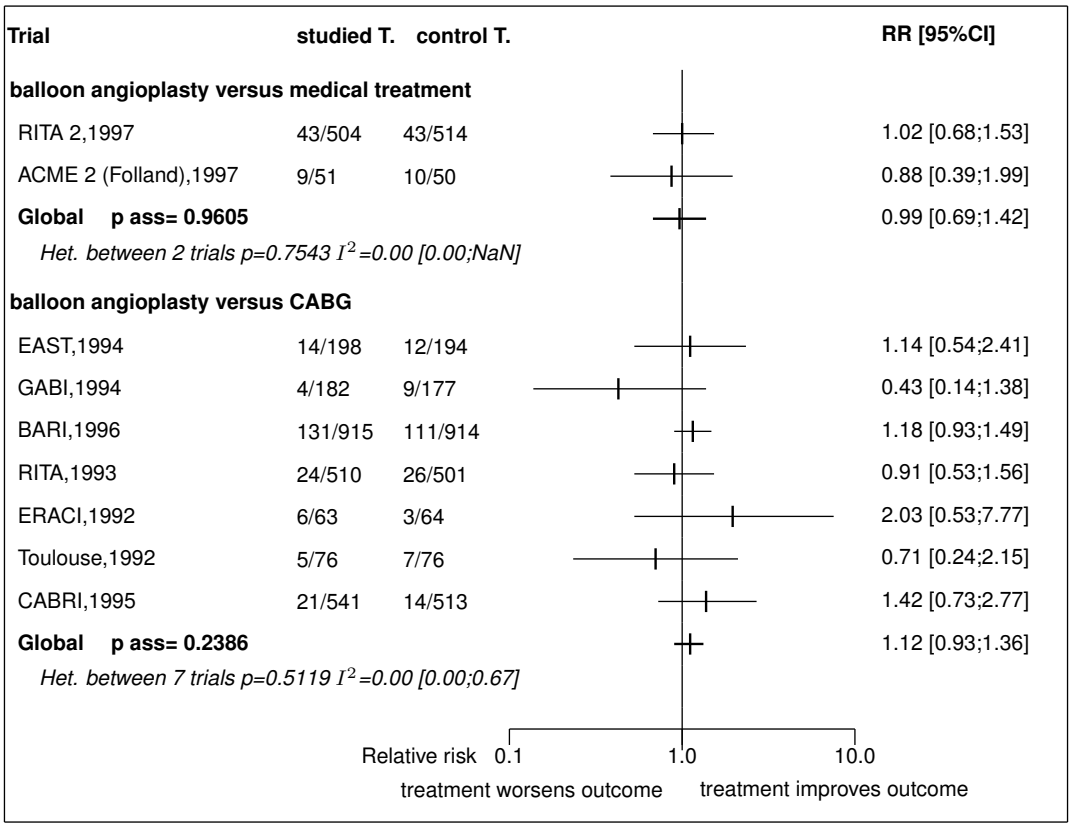


Figure 3.9: *Forest's plot for all cause death*



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[7] . Comparison of coronary bypass surgery with angioplasty in patients with multivessel disease. The Bypass Angioplasty Revascularization Investigation (BARI) Investigators. N Engl J Med 1996 Jul 25;335:217-25. [PMID=8657237]

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[11] Martuscelli E, Clementi F, Gallagher MM, D'Eliseo A, Chiricolo G, Nigri A, Marino B, Romeo F. Revascularization strategy in patients with multivessel disease and a major vessel chronically occluded; data from the CABRI trial. Eur J Cardiothorac Surg 2008;33:4-8. [PMID=17988889]

3.3 Individual trial summaries

Table 3.6: *RITA 2, 1997 - Trial synopsis*

Trial details	Patients	Treatments	Outcomes
n=1018 (504 vs. 514) **Follow-up duration:** 7y **Study design:** Randomized controlled trial Parallel groups Open Confirmatory trial at risk of bias UK **Inclusion period:** 19921996	Angina leading to admission within 90days, previous Q wave MI, no previousPTCA, no left main stem disease **Inclusion criteria:** patients with coronary artery disease proven arteriographically considered suitable for either treatment option **Exclusion criteria:** <18y, early myocardial revascularisation needed, previous myocardiadial revascularisation, life-threatening disease	**Studied treatment:** PTCA within 3 mo of the randomisation **Control treatment:** medical treatment **Concomittant treat.:**aspirin	PTCA RR=0.63 [0.50;0.80] Cardiac death or MI RR=1.07 [0.71;1.60]

References

. Coronary angioplasty versus medical therapy for angina: the second Randomised Intervention Treatment of Angina (RITA-2) trial. RITA-2 trial participants. Lancet 1997;350:461-8 [PMID=9274581]
Henderson RA, Pocock SJ, Clayton TC, Knight R, Fox KA, Julian DG, Chamberlain DA. Seven-year outcome in the RITA-2 trial: coronary angioplasty versus medical therapy. J Am Coll Cardiol 2003;42:1161-70 [PMID=14522473]

Table 3.7: *ACME 2 (Folland), 1997 - Trial synopsis*

Trial details	Patients	Treatments	Outcomes
n=101 (51 vs. 50) **Follow-up duration:** 5y **Study design:** Randomized controlled trial Parallel groups Open Confirmatory trial at risk of bias **Inclusion period:** 19871990	Stable angina, history of angina, MIwithin 3 months, exercise test with STdepression >3 mm, no previous PTCA; Stenosis >70% proximal two thirds,no main artery stenosis >50%, no 3vessel disease **Inclusion criteria:** Stable angina, history of angina, MIwithin 3 months, exercise test with STdepression >3 mm, no previous PTCAStenosis >70% proximal two thirds,no main artery stenosis >50%, no 3vessel disease	**Studied treatment:** PTCA **Control treatment:** medical therapy	PTCA RR=1.35 [0.59;3.07] Cardiac death or MI RR=0.98 [0.34;2.84]

References

Folland ED, Hartigan PM, Parisi AF. Percutaneous transluminal coronary angioplasty versus medical therapy for stable angina pectoris: outcomes for patients with double-vessel versus single-vessel coronary artery disease in a Veterans Affairs Cooperative randomized trial. Veterans Affairs ACME InvestigatorS. J Am Coll Cardiol 1997;29:1505-11 [PMID=9180111]
Henderson RA, Pocock SJ, Clayton TC, Knight R, Fox KA, Julian DG, Chamberlain DA. Seven-year outcome in the RITA-2 trial: coronary angioplasty versus medical therapy. J Am Coll Cardiol 2003;42:1161-70 [PMID=14522473]

Table 3.8: *EAST, 1994 - Trial synopsis*

Trial details	Patients	Treatments	Outcomes
n=392 (198 vs. 194) **Follow-up duration:** 3 y **Study design:** Randomized controlled trial Open USA	Patients with multivessels coronary artery disease	**Studied treatment:** transluminal coronary angioplasty **Control treatment:** coronary-artery bypass grafting	Cardiac death or MI RR=0.71 [0.44;1.16]

Reference

King SB 3rd, Lembo NJ, Weintraub WS, Kosinski AS, Barnhart HX, Kutner MH, Alazraki NP, Guyton RA, Zhao XQ. A randomized trial comparing coronary angioplasty with coronary bypass surgery. Emory Angioplasty versus Surgery Trial (EAST). N Engl J Med 1994 Oct 20;331:1044-50 [PMID=8090163]

Table 3.9: *GABI, 1994 - Trial synopsis*

Trial details	Patients	Treatments	Outcomes
n=359 (182 vs. 177) **Follow-up duration:** 1 y **Study design:** Randomized controlled trial Open Germany, 8 centres	Patients with symptomatic multivessel coronary disease	**Studied treatment:** Percutaneous transluminal coronary angioplasty **Control treatment:** coronary-artery bypass grafting	Cardiac death or MI RR=0.54 [0.26;1.14]

Reference

Hamm CW, Reimers J, Ischinger T, Rupprecht HJ, Berger J, Bleifeld W. A randomized study of coronary angioplasty compared with bypass surgery in patients with symptomatic multivessel coronary disease. German Angioplasty Bypass Surgery Investigation (GABI). N Engl J Med 1994 Oct 20;331:1037-43 [PMID=8090162]

Table 3.10: *BARI, 1996 - Trial synopsis*

Trial details	Patients	Treatments	Outcomes
n=1829 (915 vs. 914) **Follow-up duration:** 5.4 y **Study design:** Randomized controlled trial Open USA, Canada	Patients with multivessel disease	**Studied treatment:** PTCA **Control treatment:** CABG	

Reference

. Comparison of coronary bypass surgery with angioplasty in patients with multivessel disease. The Bypass Angioplasty Revascularization Investigation (BARI) Investigators. N Engl J Med 1996 Jul 25;335:217-25 [PMID=8657237]

Table 3.11: *RITA, 1993 - Trial synopsis*

Trial details	Patients	Treatments	Outcomes
n=1011 (510 vs. 501) **Follow-up duration:** 2.5 y (6.5y) **Study design:** Randomized controlled trial Open UK	Patients with one, two, or three diseased coronary arteries	**Studied treatment:** percutaneous transluminal coronary angioplasty **Control treatment:** coronary artery bypass surgery	Cardiac death or MI RR=1.08 [0.67;1.73]

Reference

. Coronary angioplasty versus coronary artery bypass surgery: the Randomized Intervention Treatment of Angina (RITA) trial. Lancet 1993 Mar 6;341:573-80 [PMID=8094826]

Table 3.12: *ERACI, 1992 - Trial synopsis*

Trial details	Patients	Treatments	Outcomes
n=127 (63 vs. 64) **Follow-up duration:** 3.8 y **Study design:** Randomized controlled trial Open Argentina	Patients with multivessel disease and lesions suitable for either form of therapy	**Studied treatment:** Percutaneous transluminal coronary angioplasty **Control treatment:** coronary artery bypass grafting	Cardiac death or MI RR=1.16 [0.45;3.01]

Reference

Rodriguez A, Boullon F, Perez-Balino N, Paviotti C, Liprandi MI, Palacios IF. Argentine randomized trial of percutaneous transluminal coronary angioplasty versus coronary artery bypass surgery in multivessel disease (ERACI): in-hospital results and 1-year follow-up. ERACI Group. J Am Coll Cardiol 1993 Oct;22:1060-7 [PMID=8409041]

Table 3.13: *Toulouse, 1992 - Trial synopsis*

Trial details	Patients	Treatments	Outcomes
n=152 (76 vs. 76) **Follow-up duration:** 2.8 y **Study design:** Randomized controlled trial Open France	Patients with multivessels coronary artery disease	**Studied treatment:** PTCA **Control treatment:** CABG	Cardiac death or MI RR=1.00 [0.34;2.96]
Reference			

Table 3.14: *CABRI, 1995 - Trial synopsis*

Trial details	Patients	Treatments	Outcomes
n=1054 (541 vs. 513) **Follow-up duration:** 1 y **Study design:** Randomized controlled trial Open Europe	Patients with symptomatic multivessel coronary disease	**Studied treatment:** percutaneous transluminal coronary angioplasty **Control treatment:** coronary artery bypass grafting	Cardiac death or MI RR=1.41 [0.89;2.22]

References

. First-year results of CABRI (Coronary Angioplasty versus Bypass Revascularisation Investigation). CABRI Trial Participants. Lancet 1995 Nov 4;346:1179-84 [PMID=7475656]
Martuscelli E, Clementi F, Gallagher MM, D'Eliseo A, Chiricolo G, Nigri A, Marino B, Romeo F. Revascularization strategy in patients with multivessel disease and a major vessel chronically occluded; data from the CABRI trial. Eur J Cardiothorac Surg 2008;33:4-8 [PMID=17988889]

4 Detailed results for PCI

4.1 Available trials

Only one trial which randomized 454 patients was identified: it compared PCI with CABG.
This trial included 454 patients and was published in 2001.
This trial was open-label in design.
It was reported in English language.
data was reported in trials;
Following tables 4.1 (page 51), 4.2 (page 51), 4.4 (page 52), and 4.3 (page 51) summarized the main characteristics of the trial including in this systematic review of randomized trials of PCI.

Table 4.1: *Treatment description - PCI - PCI*

Trial	Studied treatment	Control treatment
PCI versus CABG		
AWESOME (2001) [1, 2, 3, 4, 5, 6, 7, 8]	percutaneous coronary intervention	coronary artery bypass graft

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

Trial	Patients
PCI versus CABG	
AWESOME (2001) [1, 2, 3, 4, 5, 6, 7, 8]	High-risk patients with medically refractory ischemia

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

Trial	Design	Duration	Centre	Primary end-point
PCI versus CABG				
AWESOME, 2001 [1, 2, 3, 4, 5, 6, 7, 8] n=454	Parallel groups open confirmatory trial at risk of bias	5 years	US (Veterans Affairs Medical Centers) 16 centres	

Table 4.4: *Trial characteristics - PCI - PCI*

Trial	Age (mean, year)	Men (%)	Ejection fraction (%)	Extent of Disease	arterial grafts	stent (%)
PCI versus CABG						
AWESOME, 2001 [1, 2, 3, 4, 5, 6, 7, 8]						

4.2 Meta-analysis results

The results are detailed in table 4.5 (page 53). This table is followed by the Forest's plot corresponding to each endpoint.

PCI versus CABG

No data were presented in the 1 trial identified

Table 4.5: *Results details - PCI - PCI*

Comparison Endpoint	Effect	95% CI	p ass	p het	k	n
PCI 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] Morrison DA, Sethi G, Sacks J, Henderson W, Grover F, Sedlis S, Esposito R, Ramanathan K, Weiman D, Saucedo J, Antakli T, Paramesh V, Pett S, Vernon S, Birjiniuk V, Welt F, Krucoff M, Wolfe W, Lucke JC, Mediratta S, Booth D, Barbiere C, Lewis D. Percutaneous coronary intervention versus coronary artery bypass graft surgery for patients with medically refractory myocardial ischemia and risk factors for adverse outcomes with bypass: a multicenter, randomized trial. Investigators of the Department of Veterans Affairs Cooperative Study #385, the Angina With Extremely Serious Operative Mortality Evaluation (AWESOME). J Am Coll Cardiol 2001;38:143-9. [PMID=11451264]

[2] Morrison DA, Sethi G, Sacks J, Grover F, Sedlis S, Esposito R, Ramanathan KB, Weiman D, Krucoff M, Duhaylongsod F, Raya T, Pett S, Vernon S, Birjiniuk V, Booth D, Robinson C, Talley JD, Antckli T, Murphy E, Floten H, Curcovic V, Lucke JC, Lewis D, Barbier. A multicenter, randomized trial of percutaneous coronary intervention versus bypass surgery in high-risk unstable angina patients. The AWESOME (Veterans Affairs Cooperative Study #385, angina with extremely serious operative mortality evaluation) investigators from the Cooperative Studies Program of the Department of Veterans Affairs. Control Clin Trials 1999;20:601-19. [PMID=10588300]

[3] Morrison DA, Sethi G, Sacks J, Henderson WG, Grover F, Sedlis S, Esposito R. Percutaneous coronary intervention versus repeat bypass surgery for patients with medically refractory myocardial ischemia: AWESOME randomized trial and registry experience with post-CABG patients. J Am Coll Cardiol 2002;40:1951-4. [PMID=12475454]

[4] Ramanathan KB, Weiman DS, Sacks J, Morrison DA, Sedlis S, Sethi G, Henderson WG. Percutaneous intervention versus coronary bypass surgery for patients older than 70 years of age with high-risk unstable angina. Ann Thorac Surg 2005;80:1340-6. [PMID=16181866]

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[7] Sedlis SP, Ramanathan KB, Morrison DA, Sethi G, Sacks J, Henderson W. Outcome of percutaneous coronary intervention versus coronary bypass grafting for patients with low left ventricular ejection fractions, unstable angina pectoris, and risk factors for adverse outcomes with bypass (the AWESOME Randomized Trial and Registry). Am J Cardiol 2004;94:118-20. [PMID=15219521]

[8] Stroupe KT, Morrison DA, Hlatky MA, Barnett PG, Cao L, Lyttle C, Hynes DM, Henderson WG. Cost-effectiveness of coronary artery bypass grafts versus percutaneous coronary intervention for revascularization of high-risk patients. Circulation 2006;114:1251-7. [PMID=16966588]

4.3 Individual trial summaries

Table 4.6: *AWESOME, 2001 - Trial synopsis*

Trial details	Patients	Treatments	Outcomes
n=454 (222 vs. 232) **Follow-up duration:** 5 years **Study design:** Randomized controlled trial Parallel groups Open Confirmatory trial at risk of bias US (Veterans Affairs Medical Centers), 16 centres	High-risk patients with medically refractory ischemia	**Studied treatment:** percutaneous coronary intervention **Control treatment:** coronary artery bypass graft	

continued...

trial details	Patients	Treatments	Outcomes

References

Morrison DA, Sethi G, Sacks J, Henderson W, Grover F, Sedlis S, Esposito R, Ramanathan K, Weiman D, Saucedo J, Antakli T, Paramesh V, Pett S, Vernon S, Birjiniuk V, Welt F, Krucoff M, Wolfe W, Lucke JC, Mediratta S, Booth D, Barbiere C, Lewis D. Percutaneous coronary intervention versus coronary artery bypass graft surgery for patients with medically refractory myocardial ischemia and risk factors for adverse outcomes with bypass: a multicenter, randomized trial. Investigators of the Department of Veterans Affairs Cooperative Study #385, the Angina With Extremely Serious Operative Mortality Evaluation (AWESOME). J Am Coll Cardiol 2001;38:143-9 [PMID=11451264]

Morrison DA, Sethi G, Sacks J, Grover F, Sedlis S, Esposito R, Ramanathan KB, Weiman D, Krucoff M, Duhaylongsod F, Raya T, Pett S, Vernon S, Birjiniuk V, Booth D, Robinson C, Talley JD, Antckli T, Murphy E, Floten H, Curcovic V, Lucke JC, Lewis D, Barbier. A multicenter, randomized trial of percutaneous coronary intervention versus bypass surgery in high-risk unstable angina patients. The AWESOME (Veterans Affairs Cooperative Study #385, angina with extremely serious operative mortality evaluation) investigators from the Cooperative Studies Program of the Department of Veterans Affairs. Control Clin Trials 1999;20:601-19 [PMID=10588300]

Morrison DA, Sethi G, Sacks J, Henderson WG, Grover F, Sedlis S, Esposito R. Percutaneous coronary intervention versus repeat bypass surgery for patients with medically refractory myocardial ischemia: AWESOME randomized trial and registry experience with post-CABG patients. J Am Coll Cardiol 2002;40:1951-4 [PMID=12475454]

Ramanathan KB, Weiman DS, Sacks J, Morrison DA, Sedlis S, Sethi G, Henderson WG. Percutaneous intervention versus coronary bypass surgery for patients older than 70 years of age with high-risk unstable angina. Ann Thorac Surg 2005;80:1340-6 [PMID=16181866]

Rumsfeld JS, Magid DJ, Plomondon ME, Sacks J, Henderson W, Hlatky M, Sethi G, Morrison DA. Health-related quality of life after percutaneous coronary intervention versus coronary bypass surgery in high-risk patients with medically refractory ischemia. J Am Coll Cardiol 2003;41:1732-8 [PMID=12767656]

Sedlis SP, Morrison DA, Lorin JD, Esposito R, Sethi G, Sacks J, Henderson W, Grover F, Ramanathan KB, Weiman D, Saucedo J, Antakli T, Paramesh V, Pett S, Vernon S, Birjiniuk V, Welt F, Krucoff M, Wolfe W, Lucke JC, Mediratta S, Booth D, Murphy E, Ward H,. Percutaneous coronary intervention versus coronary bypass graft surgery for diabetic patients with unstable angina and risk factors for adverse outcomes with bypass: outcome of diabetic patients in the AWESOME randomized trial and registry. J Am Coll Cardiol 2002;40:1555-66 [PMID=12427406]

Sedlis SP, Ramanathan KB, Morrison DA, Sethi G, Sacks J, Henderson W. Outcome of percutaneous coronary intervention versus coronary bypass grafting for patients with low left ventricular ejection fractions, unstable angina pectoris, and risk factors for adverse outcomes with bypass (the AWESOME Randomized Trial and Registry). Am J Cardiol 2004;94:118-20 [PMID=15219521]

Stroupe KT, Morrison DA, Hlatky MA, Barnett PG, Cao L, Lyttle C, Hynes DM, Henderson WG. Cost-effectiveness of coronary artery bypass grafts versus percutaneous coronary intervention for revascularization of high-risk patients. Circulation 2006;114:1251-7 [PMID=16966588]

5 Detailed results for PCI with drug-eluting stents

5.1 Available trials

Only one trial which randomized 1900 patients was identified: it compared PCI with drug-eluting stents with CABG.
This trial included 1900 patients and was published in 2012.
This trial was open-label in design.
It was reported in English language.
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 5.1 (page 58), 5.2 (page 58), 5.4 (page 60), and 5.3 (page 59) summarized the main characteristics of the trial including in this systematic review of randomized trials of PCI with drug-eluting stents.

Table 5.1: *Treatment description - PCI - PCI with drug-eluting stents*

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

Table 5.2: *Descriptions of participants - PCI - PCI with drug-eluting stents*

Trial	Patients
PCI with drug-eluting stents versus CABG	

continued...

Trial	Patients	
FREEDOM (2012) [1]	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 5.3: *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				
FREEDOM, 2012 [1] n=1900	Parallel groups open confirmatory trial at risk of bias	3.8 yrs (median)	international 140 centres	death, MI, stroke

Table 5.4: *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						
FREEDOM, 2012 [1]						

5.2 Meta-analysis results

The results are detailed in table 5.5 (page 61). This table is followed by the Forest's plot corresponding to each endpoint.

PCI with drug-eluting stents versus CABG

The single study 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).
The single study 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).
The single study 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 5.5: *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 5.1: *Forest's plot for long term cardiovascular events*

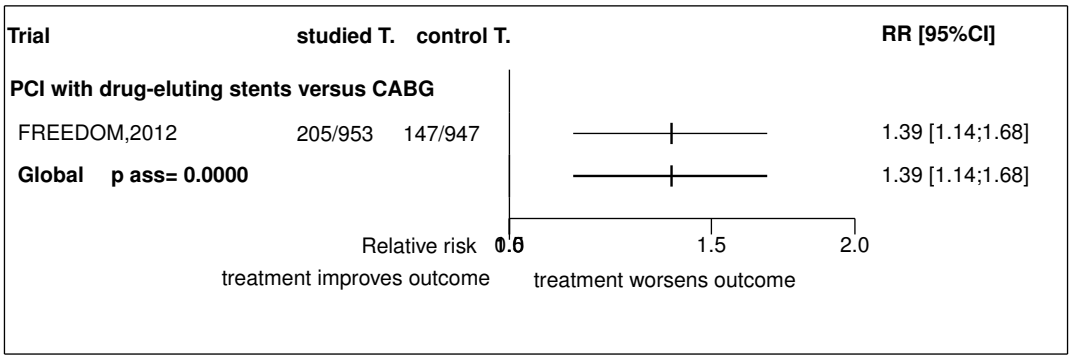


Figure 5.2: *Forest's plot for long term death*

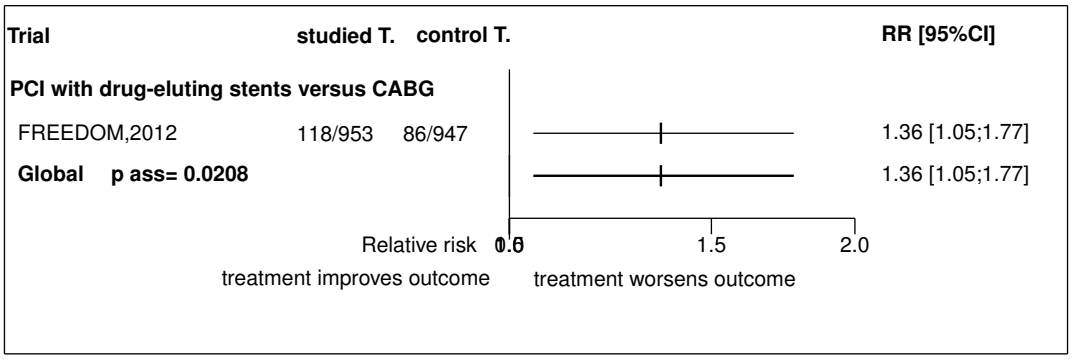
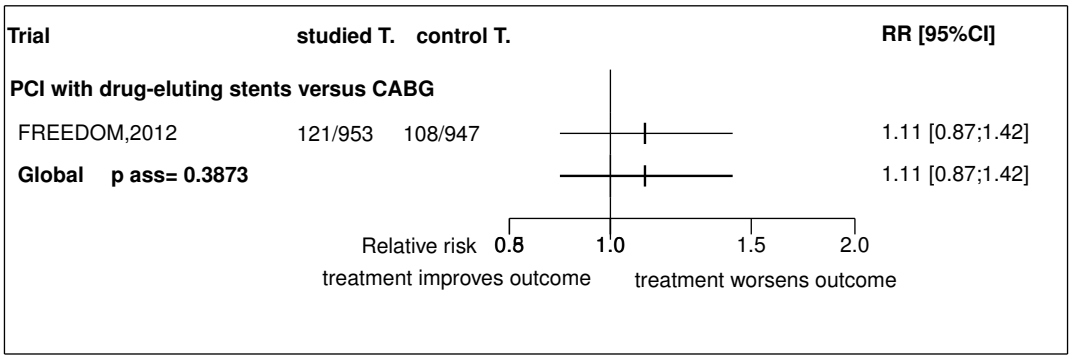


Figure 5.3: *Forest's plot for 2 yr MACE*



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[1] 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]

5.3 Individual trial summaries

Table 5.6: *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...

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]

6 Detailed results for PCI with or without stent

6.1 Available trials

A total of 5 RCTs which randomized 1072 patients were identified: all compared PCI with or without stent with medical treatment.
The average study size was 214 patients (range 41 to 408). The first study was published in 1995, and the last study was published in 2007.
All trials were open-label in design. All included studies were reported in English language. We did not found any unpublished trial.
Cardiac death data was reported in 5 trials; 5 trials reported data on PTCA; 5 trials reported data on all cause death; 5 trials reported data on cardiac death or MI; 5 trials reported data on CABG; 5 trials reported data on non fatal MI; and 1 trials reported data on myocardial infarction (fatal and non fatal).
Following tables 6.1 (page 66), 6.2 (page 66), 6.4 (page 68), and 6.3 (page 67) summarized the main characteristics of the trials including in this systematic review of randomized trials of PCI with or without stent.

Table 6.1: *Treatment description - PCI - PCI with or without stent*

Trial	Studied treatment	Control treatment
PCI with or without stent versus medical treatment		
AVERT (1995) [1]	angioplasty	atorvastatin at 80 mg per day
Dakik (1998) [2]	PTCA	intensive medical therapy
MASS II (2007) [3, 4, 5]	PCI	medical therapy
Hambrecht (2004) [6]	PCI	12 months of exercise training (20 minutes of bicycle ergometry per day)
Bech (2001) [7]	PTCA	deferral of PTCA

Table 6.2: *Descriptions of participants - PCI - PCI with or without stent*

Trial	Patients
PCI with or without stent versus medical treatment	

continued...

Trial	Patients
AVERT (1995) [1]	Angina or asymptomatic, MI orunstable angina but not within 14 days,no triple vessel disease **Inclusion criteria:** angina or asymptomatic, MI orunstable angina but not within 14 days,no triple vessel diseaseStenosis >50% in one or twovessels, no main artery stenosis **Exclusion criteria:**
Dakik (1998) [2]	Stable survivors of AMI
MASS II (2007) [3, 4, 5]	Patients with multivessel coronary artery disease with stable angina and preserved ventricular function
Hambrecht (2004) [6]	Male patients aged 70 years
Bech (2001) [7]	Patients with planned PTCA and no documented ischemia and with coronary pressurederived fractional flow reserve >0.75

Table 6.3: *Design and methodological quality of trials - PCI - PCI with or without stent*

Trial	Design	Duration	Centre	Primary endpoint
PCI with or without stent versus medical treatment				
AVERT, 1995 [1] n=341	Parallel groups open confirmatory trial at risk of bias	1.5y inclusion period: 19951996		
Dakik, 1998 [2] n=41	Parallel groups open confirmatory trial at risk of bias	1y inclusion period: 19951996		
MASS II, 2007 [3, 4, 5] n=408	Parallel groups open confirmatory trial at risk of bias	5y inclusion period: 19952000		
Hambrecht, 2004 [6] n=101	Parallel groups open confirmatory trial at risk of bias	1y inclusion period: 19972001		
Bech, 2001 [7] n=181	Parallel groups open confirmatory trial at risk of bias	2y inclusion period: ND		

Table 6.4: *Trial characteristics - PCI - PCI with or without stent*

Trial
PCI with or without stent versus medical treatment
AVERT, 1995 [1]
Dakik, 1998 [2]
MASS II, 2007 [3, 4, 5]
Hambrecht, 2004 [6]
Bech, 2001 [7]

6.2 Meta-analysis results

The results are detailed in table 6.5 (page 69). This table is followed by the Forest's plot corresponding to each endpoint.

PCI with or without stent versus medical treatment

All the 5 studies had extractable data about the number of participants with **PTCA**. The analysis detected a statistically significant difference in favor of medical treatment in PTCA, with a RR of 1.87 (95% CI 1.02 to 3.44, p=0.0436). No heterogeneity was detected (p = 0.1782, I^2 = 0.36%).
All the 5 studies had extractable data about the number of participants with **cardiac death or MI**. The analysis detected a statistically significant difference in favor of medical treatment in cardiac death or MI, with a RR of 1.79 (95% CI 1.07 to 2.98, p=0.0260). No heterogeneity was detected (p = 0.9011, I^2 = 0.00%).
Only one of the 5 studies 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 0.93 (95% CI 0.24 to 3.64, p=0.9131).
All the 5 studies had extractable data about the number of participants with **cardiac death**. When pooled together, there was no statistically significant difference between the groups in cardiac death, with a RR of 0.93 (95% CI 0.57 to 1.52, p=0.7725). No heterogeneity was detected (p = 0.9914, I^2 = 0.00%).
All the 5 studies had extractable data about the number of participants with **CABG**. When pooled together, there was no statistically significant difference between the groups in CABG, with a RR of 1.16 (95% CI 0.40 to 3.34, p=0.7804). No heterogeneity was detected (p = 0.2173, I^2 = 0.31%).
All the 5 studies had extractable data about the number of participants with **non fatal MI**. When pooled together, there was no statistically significant difference between the groups in non fatal MI, with a RR of 0.87 (95% CI 0.55 to 1.36, p=0.5344). No heterogeneity was detected (p = 0.4538, I^2 = 0.00%).
All the 5 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 0.91 (95% CI 0.56 to 1.47, p=0.6947). No heterogeneity was detected (p = 0.9700, I^2 = 0.00%).

Table 6.5: *Results details - PCI - PCI with or without stent*

Comparison Endpoint	Effect	95% CI	p ass	p het	k	n
PCI with or without stent versus medical treatment						
PTCA	RR=1.87	[1.02;3.44]	0.0436	0.1782 (I^2=0.36)	5	1072
cardiac death or MI	RR=1.79	[1.07;2.98]	0.0260	0.9011 (I^2=0.00)	5	1072
myocardial infarction (fatal and non fatal)	RR=0.93	[0.24;3.64]	0.9131	1.0000 (I^2=0.00)	1	341
cardiac death	RR=0.93	[0.57;1.52]	0.7725	0.9914 (I^2=0.00)	5	1075
CABG	RR=1.16	[0.40;3.34]	0.7804	0.2173 (I^2=0.31)	5	1072
non fatal MI	RR=0.87	[0.55;1.36]	0.5344	0.4538 (I^2=0.00)	5	1072
all cause death	RR=0.91	[0.56;1.47]	0.6947	0.9700 (I^2=0.00)	5	1072

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 6.1: *Forest's plot for PTCA*

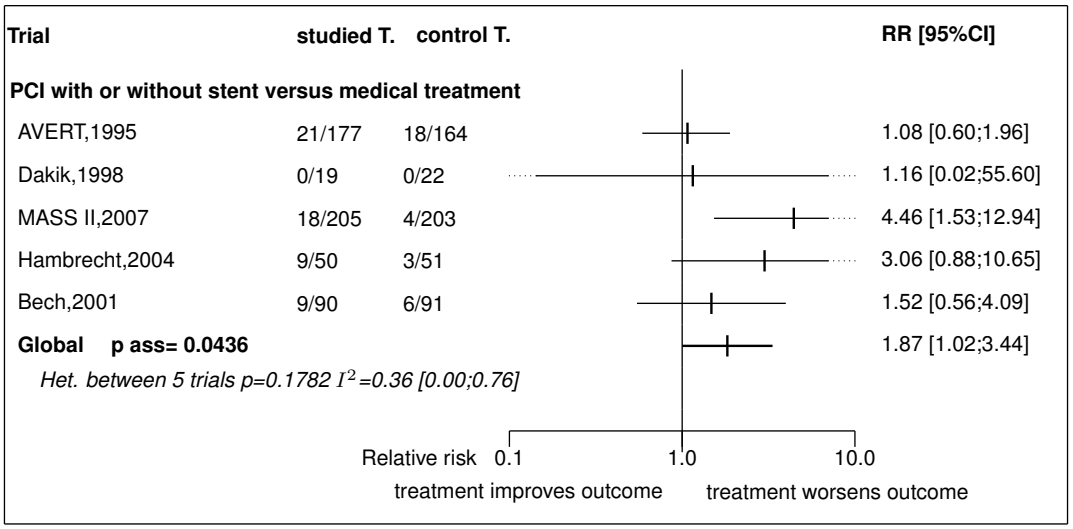


Figure 6.2: *Forest's plot for cardiac death or MI*

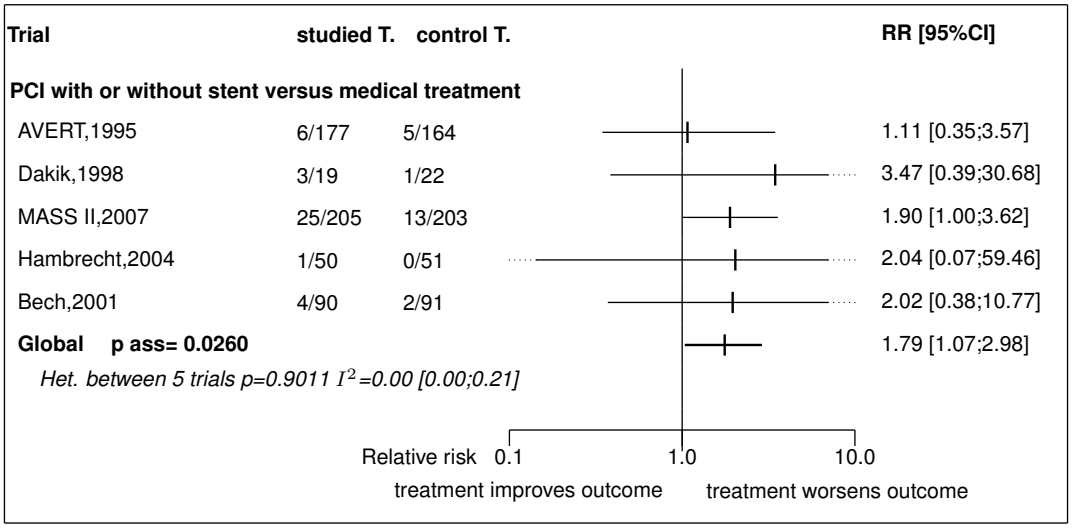


Figure 6.3: *Forest's plot for myocardial infarction (fatal and non fatal)*

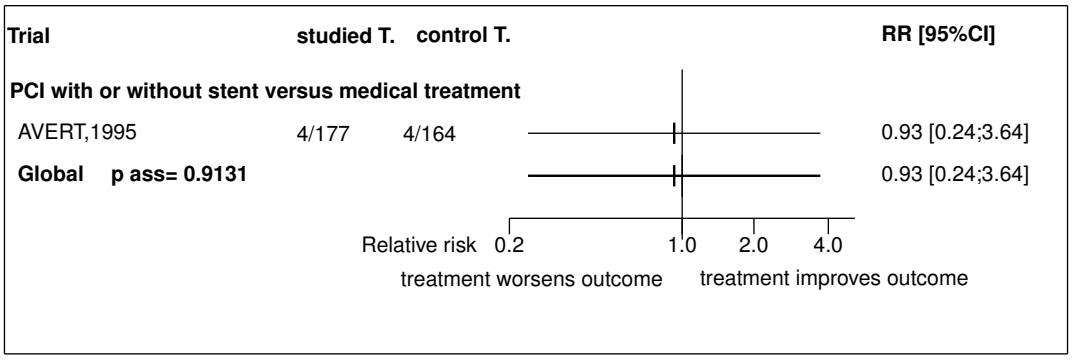


Figure 6.4: *Forest's plot for cardiac death*

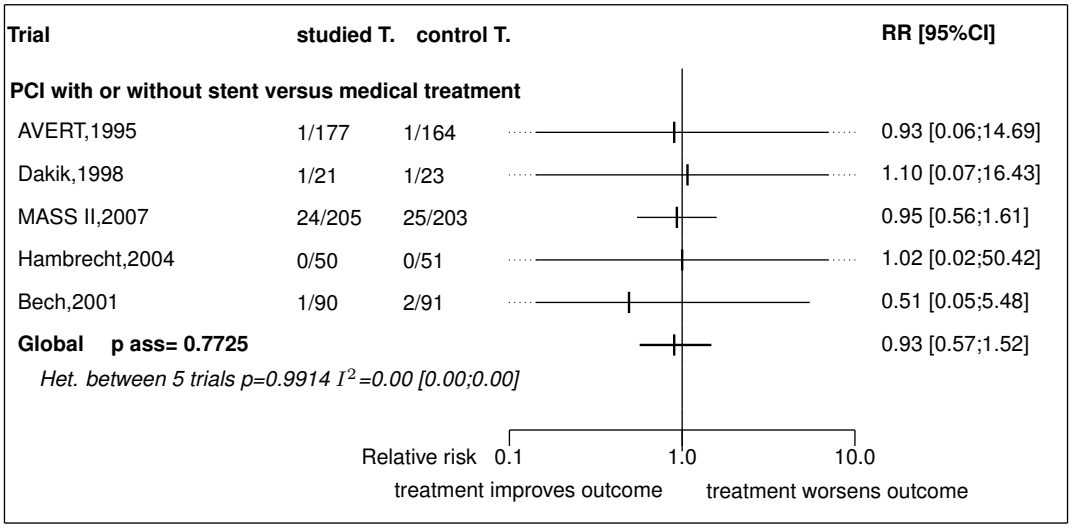


Figure 6.5: *Forest's plot for CABG*

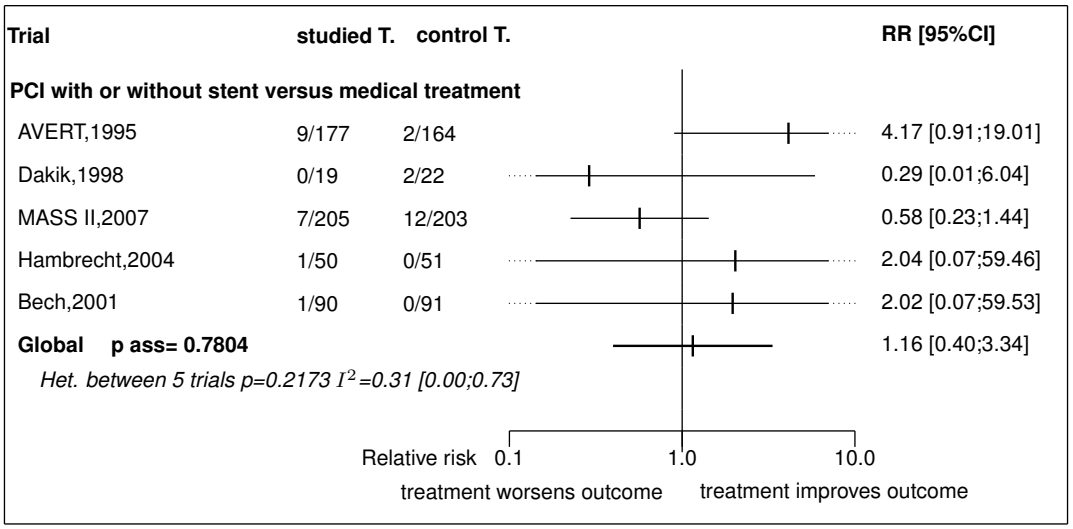


Figure 6.6: *Forest's plot for non fatal MI*

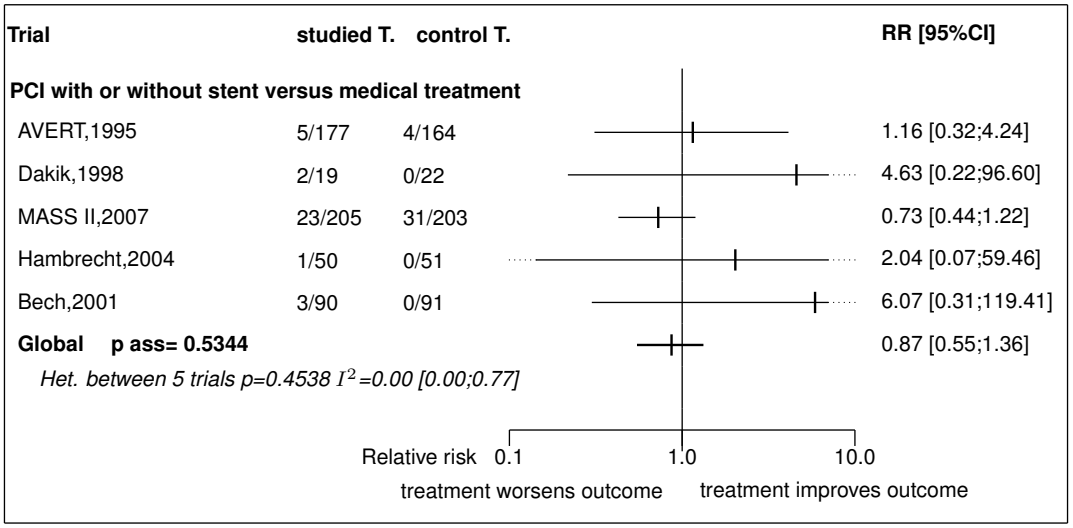
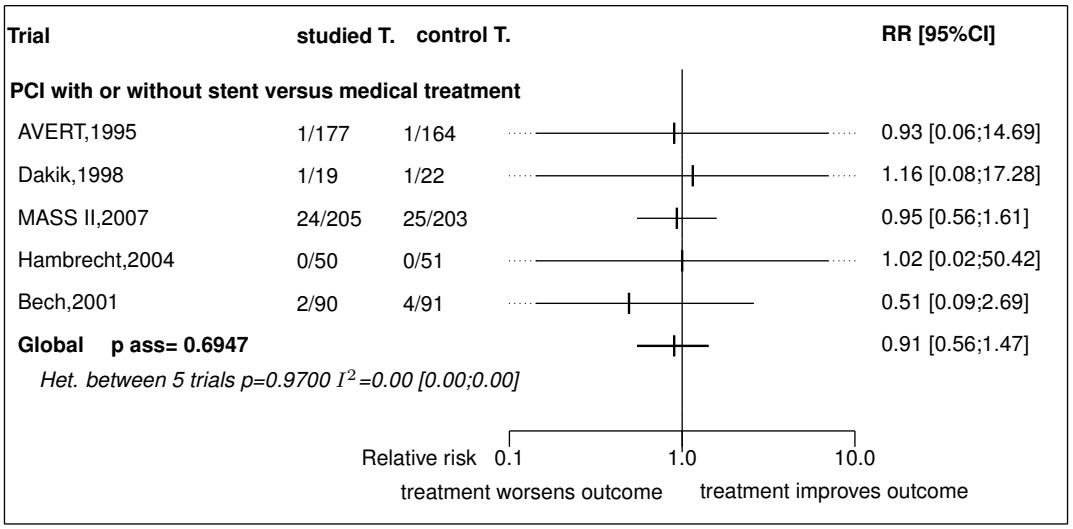


Figure 6.7: *Forest's plot for all cause death*



References

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[3] Hueb W, Lopes NH, Gersh BJ, Soares P, Machado LA, Jatene FB, Oliveira SA, Ramires JA. Five-year follow-up of the Medicine, Angioplasty, or Surgery Study (MASS II): a randomized controlled clinical trial of 3 therapeutic strategies for multivessel coronary artery disease. Circulation 2007;115:1082-9. [PMID=17339566]

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[7] Bech GJ, De Bruyne B, Pijls NH, de Muinck ED, Hoorntje JC, Escaned J, Stella PR, Boersma E, Bartunek J, Koolen JJ, Wijns W. Fractional flow reserve to determine the appropriateness of angioplasty in moderate coronary stenosis: a randomized trial. Circulation 2001;103:2928-34. [PMID=11413082]

6.3 Individual trial summaries

Table 6.6: *AVERT, 1995 - Trial synopsis*

Trial details	Patients	Treatments	Outcomes
n=341 (177 vs. 164) **Follow-up duration:** 1.5y **Study design:** Randomized controlled trial Parallel groups Open Confirmatory trial at risk of bias **Inclusion period:** 19951996	Angina or asymptomatic, MI orunstable angina but not within 14 days,no triple vessel disease **Inclusion criteria:** Angina or asymptomatic, MI orunstable angina but not within 14 days,no triple vessel diseaseStenosis >50% in one or twovessels, no main artery stenosis	**Studied treatment:** angioplasty **Control treatment:** atorvastatin at 80 mg per day	PTCA RR=1.08 [0.60;1.96] Cardiac death or MI RR=1.11 [0.35;3.57]

Reference

Pitt B, Waters D, Brown WV, van Boven AJ, Schwartz L, Title LM, Eisenberg D, Shurzinske L, McCormick LS. Aggressive lipid-lowering therapy compared with angioplasty in stable coronary artery disease. Atorvastatin versus Revascularization Treatment Investigators. N Engl J Med 1999;341:70-6 [PMID=10395630]

Table 6.7: *Dakik, 1998 - Trial synopsis*

Trial details	Patients	Treatments	Outcomes
n=41 (19 vs. 22) **Follow-up duration:** 1y **Study design:** Randomized controlled trial Parallel groups Open Confirmatory trial at risk of bias **Inclusion period:** 19951996	Stable survivors of AMI	**Studied treatment:** PTCA **Control treatment:** intensive medical therapy	Cardiac death or MI RR=3.47 [0.39;30.68]

Reference

Dakik HA, Kleiman NS, Farmer JA, He ZX, Wendt JA, Pratt CM, Verani MS, Mahmarian JJ. Intensive medical therapy versus coronary angioplasty for suppression of myocardial ischemia in survivors of acute myocardial infarction: a prospective, randomized pilot study. Circulation 1998;98:2017-23 [PMID=9808599]

Table 6.8: *MASS II, 2007 - Trial synopsis*

Trial details	Patients	Treatments	Outcomes
n=408 (205 vs. 203) **Follow-up duration:** 5y **Study design:** Randomized controlled trial Parallel groups Open Confirmatory trial at risk of bias **Inclusion period:** 19952000	Patients with multivessel coronary artery disease with stable angina and preserved ventricular function	**Studied treatment:** PCI **Control treatment:** medical therapy	PTCA RR=4.46 [1.53;12.94] Cardiac death or MI RR=1.90 [1.00;3.62]

References

Hueb W, Lopes NH, Gersh BJ, Soares P, Machado LA, Jatene FB, Oliveira SA, Ramires JA. Five-year follow-up of the Medicine, Angioplasty, or Surgery Study (MASS II): a randomized controlled clinical trial of 3 therapeutic strategies for multivessel coronary artery disease. Circulation 2007;115:1082-9 [PMID=17339566]
Hueb W, Soares PR, Gersh BJ, Csar LA, Luz PL, Puig LB, Martinez EM, Oliveira SA, Ramires JA. The medicine, angioplasty, or surgery study (MASS-II): a randomized, controlled clinical trial of three therapeutic strategies for multivessel coronary artery disease: one-year results. J Am Coll Cardiol 2004;43:1743-51 [PMID=15145093]
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Table 6.9: *Hambrecht, 2004 - Trial synopsis*

Trial details	Patients	Treatments	Outcomes
n=101 (50 vs. 51) **Follow-up duration:** 1y **Study design:** Randomized controlled trial Parallel groups Open Confirmatory trial at risk of bias **Inclusion period:** 19972001	Male patients aged 70 years	**Studied treatment:** PCI **Control treatment:** 12 months of exercise training (20 minutes of bicycle ergometry per day)	PTCA RR=3.06 [0.88;10.65]

Reference

Hambrecht R, Walther C, Möbius-Winkler S, Gielen S, Linke A, Conradi K, Erbs S, Kluge R, Kendziorra K, Sabri O, Sick P, Schuler G. Percutaneous coronary angioplasty compared with exercise training in patients with stable coronary artery disease: a randomized trial. Circulation 2004;109:1371-8 [PMID=15007010]

Table 6.10: *Bech, 2001 - Trial synopsis*

Trial details	Patients	Treatments	Outcomes
n=181 (90 vs. 91) **Follow-up duration:** 2y **Study design:** Randomized controlled trial Parallel groups Open Confirmatory trial at risk of bias **Inclusion period:** ND	Patients with planned PTCA and no documented ischemia and with coronary pressurederived fractional flow reserve >0.75	**Studied treatment:** PTCA **Control treatment:** deferral of PTCA	PTCA RR=1.52 [0.56;4.09] Cardiac death or MI RR=2.02 [0.38;10.77]

Reference

Bech GJ, De Bruyne B, Pijls NH, de Muinck ED, Hoorntje JC, Escaned J, Stella PR, Boersma E, Bartunek J, Koolen JJ, Wijns W. Fractional flow reserve to determine the appropriateness of angioplasty in moderate coronary stenosis: a randomized trial. Circulation 2001;103:2928-34 [PMID=11413082]

7 Detailed results for stent

7.1 Available trials

A total of 6 RCTs which randomized 3605 patients were identified: all compared stent with CABG.
The average study size was 600 patients (range 44 to 1205). The first study was published in 2001, and the last study was published in 2008.
All trials were 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 3 trials; 3 trials reported data on long term death; 3 trials reported data on 1 year death from any cause; 2 trials reported data on 1 year revascularization; 2 trials reported data on 1 year MI; 2 trials reported data on 1 year event; 2 trials reported data on long term MI; 1 trials reported data on ; 1 trials reported data on all cause death; and 1 trials reported data on 2 yr MACE.
Following tables 7.1 (page 81), 7.2 (page 82), 7.4 (page 84), and 7.3 (page 82) 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 CABG		
ARTS (2001) [1, 2, 3, 4, 5]	Palmaz-Schatz Crown/Cross flex (Cordis)	Conventional CABG
CARDia (PCI) (2008) [6] [b]	PCI plus stenting (and routine abciximab) bare metal stent or sirolimus-coated stents (CYPHER) and abciximab	CABG
ERACI II (2003) [7, 8]	Gianturco Robin II (Cook) Primary device	Conventional CABG
MASS II (2007) [9, 10] [d]	PCI (73% stent)	CABG
Myoprotect (2004) [11]	percutaneous transluminal coronary angioplasty/stent	CABG
SOS (2002) [12, 13, 14, 15, 16, 17]	Stent No restriction on type of stent	CABG No restriction on type of surgical technique (3% of procedures OPCAB)

b) BMS n=72, CYPHER n=180 d) 3 arms: PCI, CABGand medical treatment

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

Trial	Patients	
Stent versus CABG		
ARTS (2001) [1, 2, 3, 4, 5]	Multi vessel disease with 2 or more de novo lesion in different major arteries Total occlusion <1month	
	Inclusion criteria:	**Exclusion criteria:** transmural MI 1 week
CARDia (PCI) (2008) [6]	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
ERACI II (2003) [7, 8]	Multi vessel disease Angina CSS III-IV; no angina but large area of heart at risk; unstable =1 vessel to be treated Lesion >3.0mm	
	Inclusion criteria:	**Exclusion criteria:** MI <=24h
MASS II (2007) [9, 10]	Patients with multivessel coronary artery disease with stable angina and preserved ventricular function	
	Inclusion criteria:	**Exclusion criteria:** MI/unstable angina requiring emergency revascularization
Myoprotect (2004) [11]	Patients with symptomatic main-stem and main-stem-equivalent lesions with substantially increased risk for bypass surgery	
SOS (2002) [12, 13, 14, 15, 16, 17]	Multiple vessel disease Symptomatic 1 or more vessel suitable for stenting	
	Inclusion criteria:	**Exclusion criteria:** MI <=48h

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

Trial	Design	Duration	Centre	Primary endpoint
Stent versus CABG				
ARTS, 2001 [1, 2, 3, 4, 5] n=1205	parallel group open	1 year	International Multicentre	major adverse cardiac and cerebrovascular events at one year
CARDia (PCI), 2008 [6] n=510	Parallel groups open confirmatory trial at risk of bias	1 y	UK, Ireland 24 centres	death, stroke, and MI
ERACI II, 2003 [7, 8] n=450	parallel group open confirmatory trial at risk of bias	30d, 1year	Argentinad Multicentre	

continued...

Trial	Design	Duration	Centre	Primary endpoint
MASS II, 2007 [9, 10] n=408	Parallel groups open confirmatory trial at risk of bias	5y (1y) inclusion period: May 1995 - may 2000	South America single-center	MACE
Myoprotect, 2004 [11] n=44	Parallel groups open exploratory trial	1 year	Europe single center	not defined
SOS, 2002 [12, 13, 14, 15, 16, 17] n=988	parallel group open confirmatory trial at risk of bias	3 years	Canada, United Kingdom, Europe Multicentre	repeat revascularisation

Table 7.4: *Trial characteristics - PCI - stent*

Trial	Age (mean, year)	Men (%)	Ejection fraction (%)	Extent of Disease	arterial grafts	stent (%)
Stent versus CABG						
ARTS, 2001 [1, 2, 3, 4, 5]						
CARDia (PCI), 2008 [6]						
ERACI II, 2003 [7, 8]						
MASS II, 2007 [9, 10]						
Myoprotect, 2004 [11]						
SOS, 2002 [12, 13, 14, 15, 16, 17]						

7.2 Meta-analysis results

The results are detailed in table 7.5 (page 86). This table is followed by the Forest's plot corresponding to each endpoint.

Stent versus CABG

A total of 3 of the 6 studies eligible for this comparison provided data on **1 year event**. The analysis detected a statistically significant difference in favor of CABG in 1 year event, with a RR of 1.82 (95% CI 1.42 to 2.34, p=0.0000). No heterogeneity was detected (p = 0.1740, I^2 = 0.43%).
Only one of the 6 studies eligible for this comparison provided data on . The analysis detected a statistically significant difference in favor of CABG in , with a RR of 2.01 (95% CI 1.63 to 2.47, p=0.0000).
A total of 3 of the 6 studies 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 4.88 (95% CI 3.62 to 6.58, p=0.0000). No heterogeneity was detected (p = 0.6615, I^2 = 0.00%).
A total of 4 of the 6 studies eligible for this comparison provided data on **long term cardiovascular events**. When pooled together, there was no statistically significant difference between the groups in long term cardiovascular events, with a RR of 1.13 (95% CI 0.81 to 1.56, p=0.4791). A random effect model was used because there was a substantial statistical heterogeneity detected between the studies (p = 0.0418, I^2 = 0.63%).
A total of 3 of the 6 studies eligible for this comparison provided data on **1 year death from any cause**. When pooled together, there was no statistically significant difference between the groups in 1 year death from any cause, with a RR of 0.94 (95% CI 0.32 to 2.75, p=0.9155). A random effect model was used because there was a substantial statistical heterogeneity detected between the studies (p = 0.0136, I^2 = 0.77%).
A total of 2 of the 6 studies eligible for this comparison provided data on **1 year MI**. When pooled together, there was no statistically significant difference between the groups in 1 year MI, with a RR of 0.91 (95% CI 0.46 to 1.83, p=0.7944). No heterogeneity was detected (p = 0.0501, I^2 = 0.74%).
A total of 2 of the 6 studies eligible for this comparison provided data on **long term MI**. When pooled together, there was no statistically significant difference between the groups in long term MI, with a RR of 0.92 (95% CI 0.47 to 1.82, p=0.8166). A random effect model was used because there was a substantial statistical heterogeneity detected between the studies (p = 0.0386, I^2 = 0.77%).
A total of 4 of the 6 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 1.00 (95% CI 0.66 to 1.50, p=0.9849). No heterogeneity was detected (p = 0.0507, I^2 = 0.61%).
Only one of the 6 studies eligible for this comparison provided data on **2 yr MACE**. The analysis detected a statistically significant difference in favor of CABG in 2 yr MACE, with a RR of 2.01 (95% CI 1.60 to 2.51, p=0.0000).
Only one of the 6 studies 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 1.49 (95% CI 0.81 to 2.71, p=0.1977).

Table 7.5: *Results details - PCI - stent*

Comparison Endpoint	Effect	95% CI	p ass	p het	k	n
stent versus CABG						
1 year event	RR=1.82	[1.42;2.34]	0.0000	0.1740 (I^2=0.43)	3	2703
	RR=2.01	[1.63;2.47]	0.0000	1.0000 (I^2=1.00)	1	1205
1 year revascularization	RR=4.88	[3.62;6.58]	0.0000	0.6615 (I^2=0.00)	3	2703
long term cardiovascular events	RR=1.13	[0.81;1.56]	0.4791	0.0418 (I^2=0.63)	4	3051
1 year death from any cause	RR=0.94	[0.32;2.75]	0.9155	0.0136 (I^2=0.77)	3	2643
1 year MI	RR=0.91	[0.46;1.83]	0.7944	0.0501 (I^2=0.74)	2	2193
long term MI	RR=0.92	[0.47;1.82]	0.8166	0.0386 (I^2=0.77)	2	2193
long term death	RR=1.00	[0.66;1.50]	0.9849	0.0507 (I^2=0.61)	4	3051
2 yr MACE	RR=2.01	[1.60;2.51]	0.0000	1.0000 (I^2=0.00)	1	1205
all cause death	RR=1.49	[0.81;2.71]	0.1977	1.0000 (I^2=0.00)	1	408

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 1 year event*

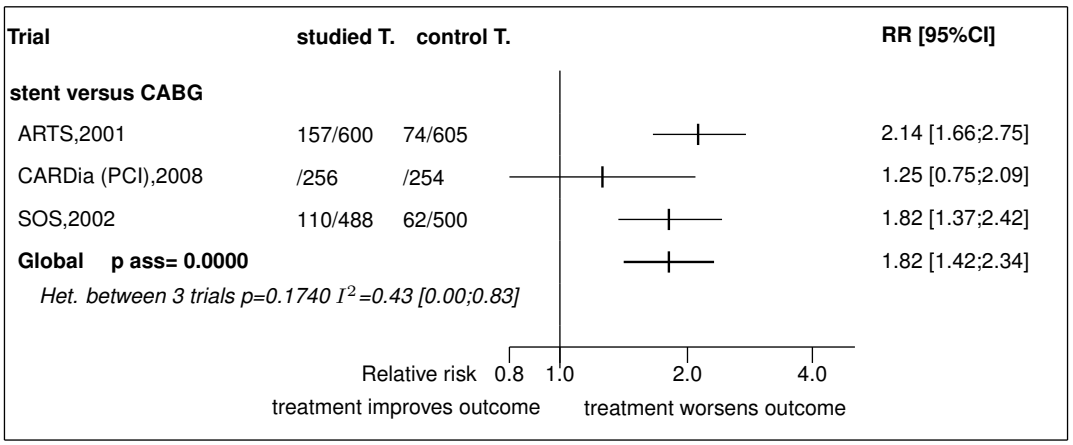


Figure 7.2: *Forest's plot for*

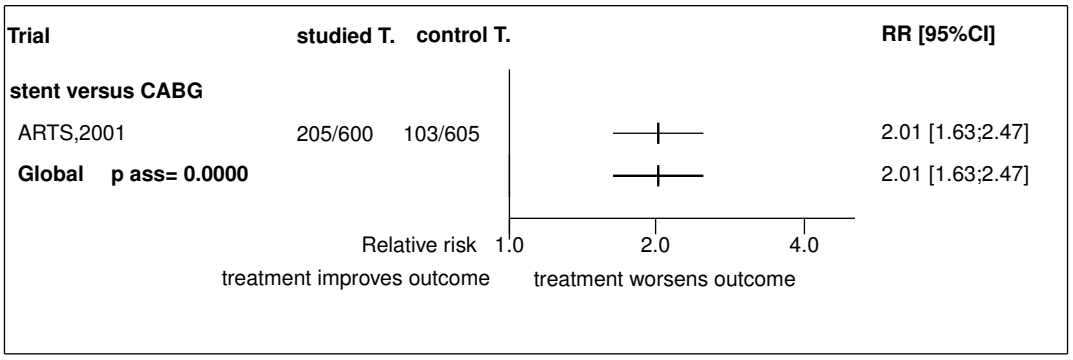


Figure 7.3: *Forest's plot for 1 year revascularization*

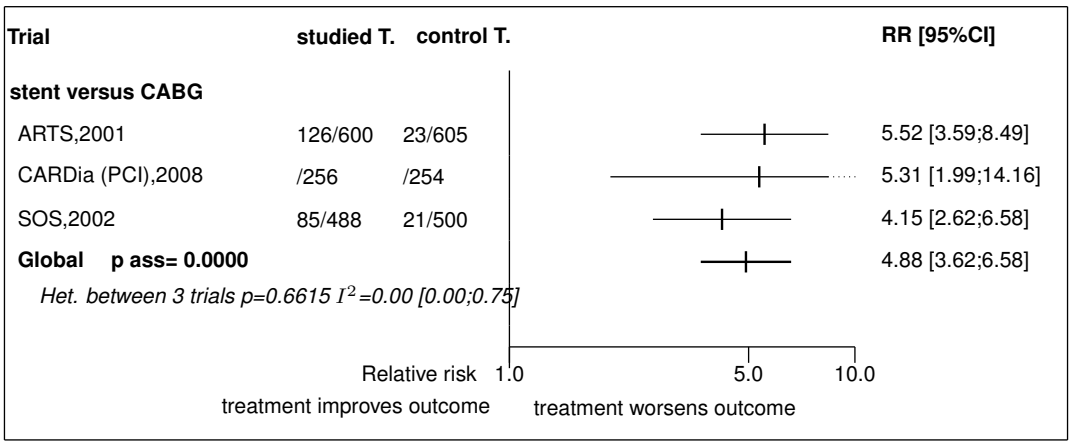


Figure 7.4: *Forest's plot for long term cardiovascular events*

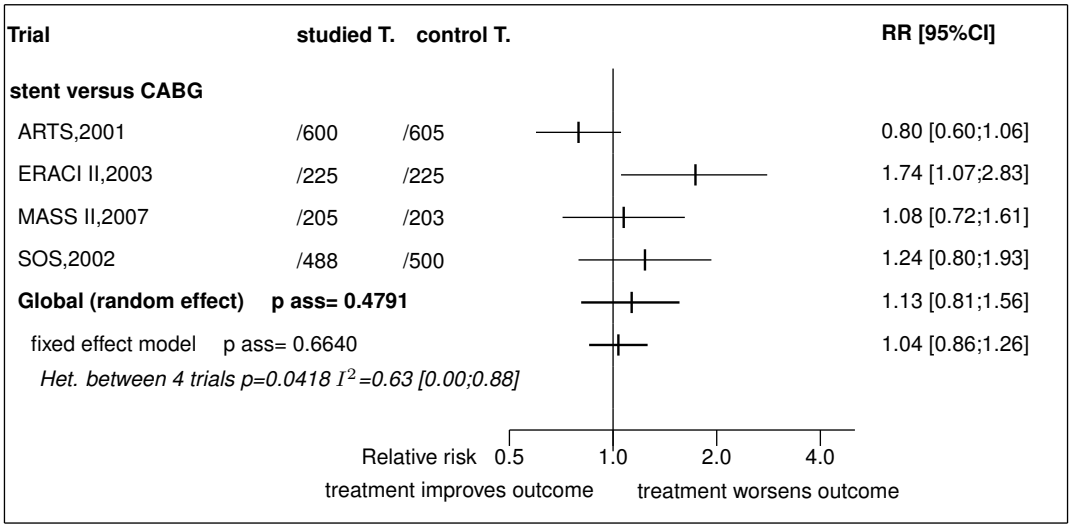


Figure 7.5: *Forest's plot for 1 year death from any cause*

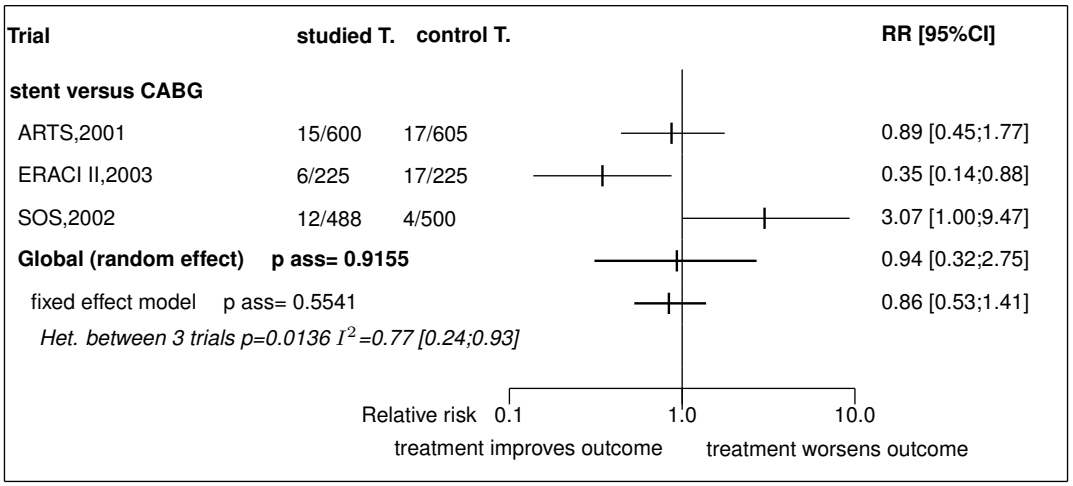


Figure 7.6: *Forest's plot for 1 year MI*

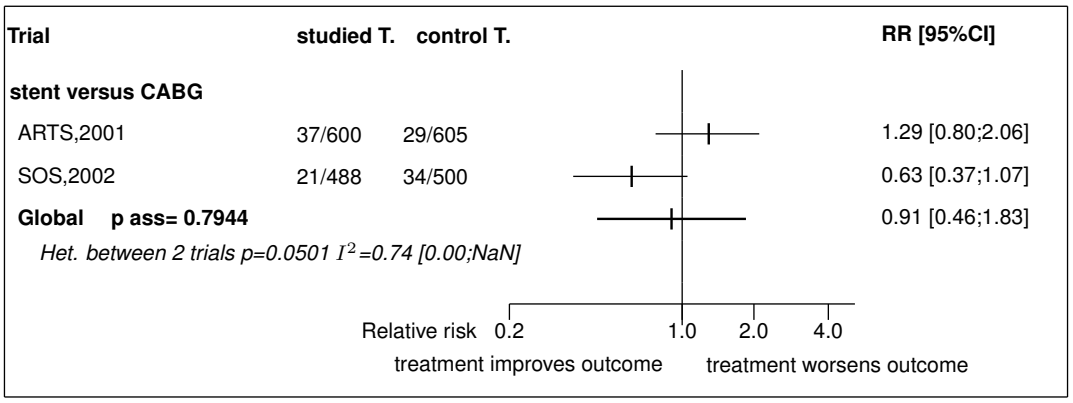


Figure 7.7: *Forest's plot for long term MI*

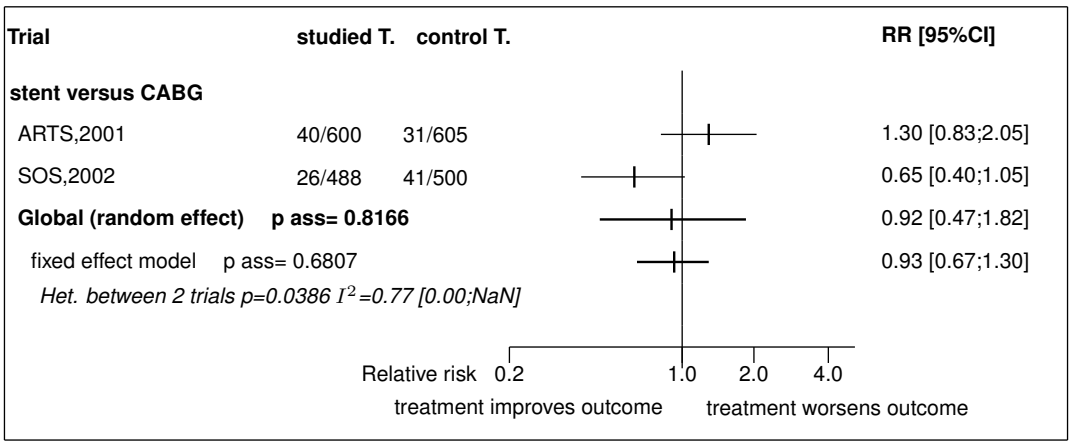


Figure 7.8: *Forest's plot for long term death*

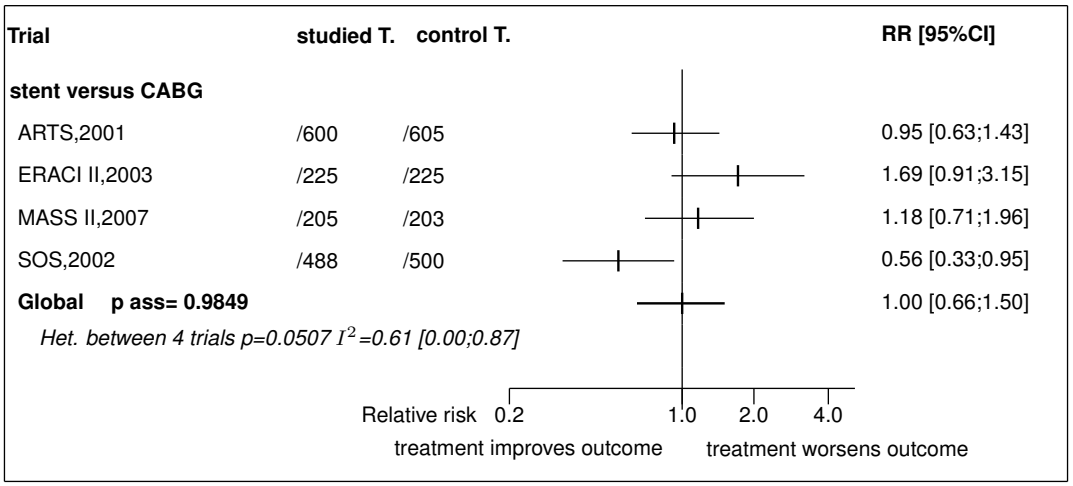


Figure 7.9: *Forest's plot for 2 yr MACE*

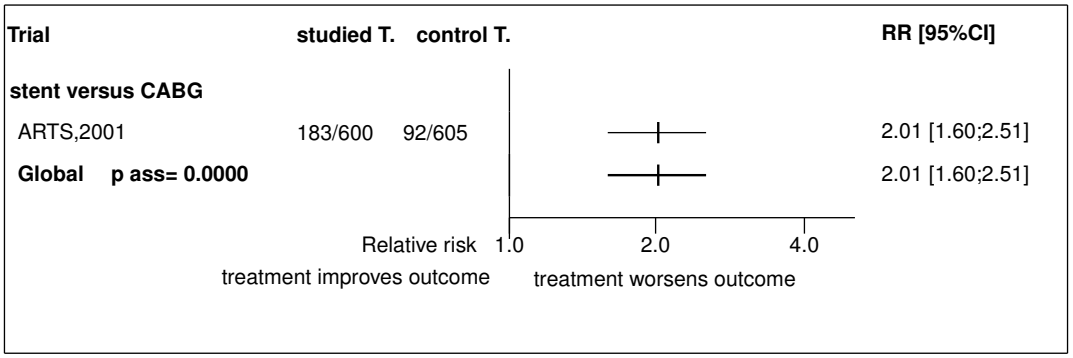
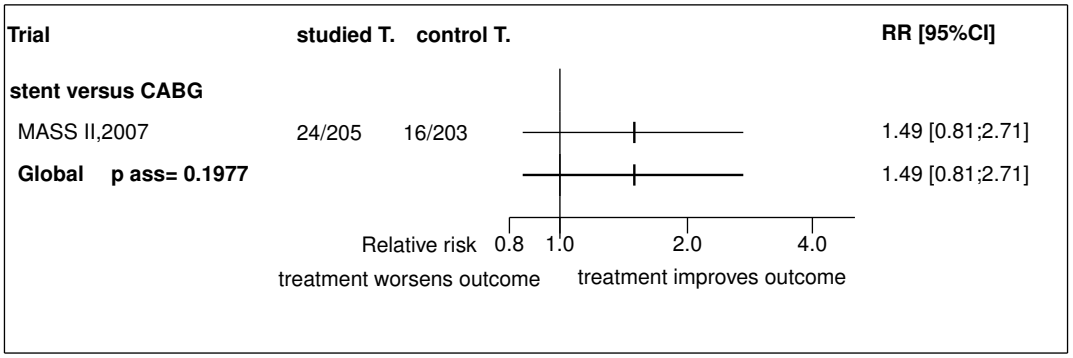


Figure 7.10: *Forest's plot for all cause death*



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7.3 Individual trial summaries

Table 7.6: *ARTS, 2001 - Trial synopsis*

Trial details	Patients	Treatments	Outcomes
n=1205 (600 vs. 605) **Follow-up duration:** 1 year **Study design:** Randomized controlled trial parallel group Open International, Multicentre	Multi vessel disease with 2 or more de novo lesion in different major arteries Total occlusion <1month **Exclusion criteria:** Transmural MI 1 week	**Studied treatment:** Palmaz-Schatz Crown/Cross flex (Cordis) **Control treatment:** Conventional CABG	1 year event RR=2.14 [1.66;2.75] RR=2.01 [1.63;2.47] 1 year revascularization RR=5.52 [3.59;8.49]

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Table 7.7: *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

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Table 7.8: *ERACI II, 2003 - Trial synopsis*

Trial details	Patients	Treatments	Outcomes
n=450 (225 vs. 225) **Follow-up duration:** 30d, 1year **Study design:** Randomized controlled trial parallel group Open Confirmatory trial at risk of bias Argentinad, Multicentre	Multi vessel disease Angina CSS III-IV; no angina but large area of heart at risk; unstable =1 vessel to be treated Lesion >3.0mm **Exclusion criteria:** MI <=24h	**Studied treatment:** Gianturco Robin II (Cook) Primary device **Control treatment:** Conventional CABG	

References

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Table 7.9: *MASS II, 2007 - Trial synopsis*

Trial details	Patients	Treatments	Outcomes
n=408 (205 vs. 203) **Follow-up duration:** 5y (1y) **Study design:** Randomized controlled trial Parallel groups Open Confirmatory trial at risk of bias South America, single-center **Inclusion period:** May 1995 - may 2000	Patients with multivessel coronary artery disease with stable angina and preserved ventricular function **Exclusion criteria:** MI/unstable angina requiring emergency revascularization	**Studied treatment:** PCI (73% stent) **Control treatment:** CABG **note:** 3 arms: PCI, CABGand medical treatment	

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Table 7.10: *Myoprotect, 2004 - Trial synopsis*

Trial details	Patients	Treatments	Outcomes
n=44 (23 vs. 21) **Follow-up duration:** 1 year **Study design:** Randomized controlled trial Parallel groups Open Exploratory trial Europe, single center	Patients with symptomatic main-stem and main-stem-equivalent lesions with substantially increased risk for bypass surgery	**Studied treatment:** percutaneous transluminal coronary angioplasty/stent **Control treatment:** CABG	

Reference

Pohl T, Giehrl W, Reichart B, Kupatt C, Raake P, Paul S, Reichenspurner H, Steinbeck G, Boekstegers P. Retroinfusion-supported stenting in high-risk patients for percutaneous intervention and bypass surgery: results of the prospective randomized myoprotect I study. Catheter Cardiovasc Interv 2004;62:323-30 [PMID=15224298]

Table 7.11: *SOS, 2002 - Trial synopsis*

Trial details	Patients	Treatments	Outcomes
n=988 (488 vs. 500) **Follow-up duration:** 3 years **Study design:** Randomized controlled trial parallel group Open Confirmatory trial at risk of bias Canada, United Kingdom, Europe, Multicentre	Multiple vessel disease Symptomatic 1 or more vessel suitable for stenting **Exclusion criteria:** MI <=48h	**Studied treatment:** Stent No restriction on type of stent **Control treatment:** CABG No restriction on type of surgical technique (3% of procedures OPCAB)	1 year event RR=1.82 [1.37;2.42] 1 year revascularization RR=4.15 [2.62;6.58]

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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
1 year event	RR=1.82	1.42;2.34	0.0000	0.1740 (0.43)	3	2703
	RR=2.01	1.63;2.47	0.0000	1.0000 (1.00)	1	1205
1 year revascularization	RR=4.88	3.62;6.58	0.0000	0.6615 (0.00)	3	2703
long term cardiovascular events	RR=1.19 [1]	0.91;1.55	0.2079	0.0141 (0.68) †	5	4951
cardiac death or MI	RR=0.96	0.72;1.29	0.7937	0.2365 (0.26)	6	3095
angina (grade 2 or worse) in first year	RR=1.56	1.20;2.04	0.0000	0.1159 (0.49)	4	2610
1 year death from any cause	RR=0.94 [2]	0.32;2.75	0.9155	0.0136 (0.77) †	3	2643
1 year MI	RR=0.91	0.46;1.83	0.7944	0.0501 (0.74)	2	2193
long term MI	RR=0.92 [3]	0.47;1.82	0.8166	0.0386 (0.77) †	2	2193
long term death	RR=1.08 [4]	0.78;1.50	0.6358	0.0261 (0.64) †	5	4951
2 yr MACE	RR=1.50 [5]	0.84;2.67	0.1702	0.0000 (0.92) †	2	3105
CABG	RR=16.04	9.73;26.43	0.0000	0.8372 (0.00)	6	3095
angina	RR=1.31	0.90;1.93	0.1630	0.1638 (0.48)	2	1349
all cause death	RR=1.15	0.96;1.38	0.1306	0.5381 (0.00)	8	5332

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 medical treatment

[1] with a random model ($\tau^2 = NaN$). The results with a fixed effect model was RRFE=1.20 95% CI 1.05;1.37
[2] with a random model ($\tau^2 = NaN$). The results with a fixed effect model was RRFE=0.86 95% CI 0.53;1.41
[3] with a random model ($\tau^2 = NaN$). The results with a fixed effect model was RRFE=0.93 95% CI 0.67;1.30
[4] with a random model ($\tau^2 = NaN$). The results with a fixed effect model was RRFE=1.14 95% CI 0.95;1.37
[5] with a random model ($\tau^2 = NaN$). The results with a fixed effect model was RRFE=1.53 95% CI 1.30;1.81

Table 8.2: *All PCIversus medical treatment*

Endpoint	Effect	95% CI	p ass	p het (I^2)	k	n
PTCA	RR=1.42 [6]	0.79;2.55	0.2438	0.0011 (0.73) †	7	2191
cardiac death or MI	RR=1.27	0.94;1.72	0.1203	0.7167 (0.00)	7	2191
myocardial infarction (fatal and non fatal)	RR=1.01	0.36;2.84	0.9803	0.0941 (0.58)	3	1460
cardiac death	RR=0.90	0.62;1.30	0.5649	0.9971 (0.00)	6	2093
CABG	RR=1.07	0.70;1.64	0.7647	0.3561 (0.10)	7	2191
non fatal MI	RR=1.06	0.77;1.47	0.7154	0.4642 (0.00)	7	2191
angina	RR=0.89	0.72;1.09	0.2602	0.1824 (0.44)	2	1119
all cause death	RR=0.96	0.72;1.28	0.7829	0.9942 (0.00)	7	2191

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

Only one ongoing study was identified. A brief description of this trial is given table 9.1

Table 9.1: *Ongoing studies for PCI*

Study	Description
ISCHEMIA	invasive strategy, consisting of early routine cardiac catheterization followed by revascularization plus optimal medical therapy (OMT) and lifestyle changes **vs.** conservative strategy of optimal medical therapy and lifestyle changes in which invasive procedures will be performed only after failure of OMT patients with stable ischemic heart disease and moderate to severe ischemia

10 Excluded studies

No trial was excluded.

[6] with a random model ($\tau^2 = NaN$). The results with a fixed effect model was RRFE=0.82 95% CI 0.67;1.00

References