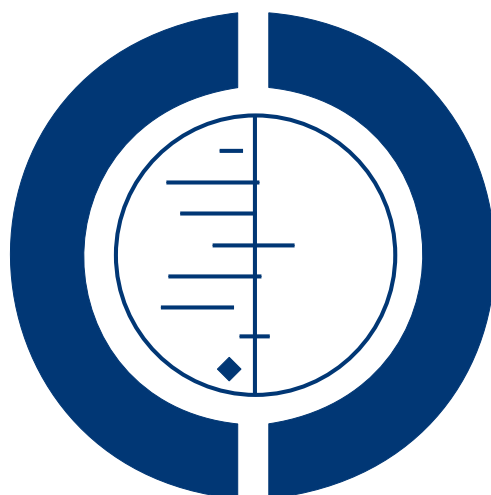


Primary stenting versus primary balloon angioplasty for treating acute myocardial infarction (Review)

Nordmann AJ, Bucher H, Hengstler P, Harr T, Young J



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ABSTRACT

Background

Balloon angioplasty following myocardial infarction (MI) reduces death, non-fatal MI and stroke compared to thrombolytic reperfusion. However up to 50% of patients experience restenosis and 3% to 5% recurrent myocardial infarction. Therefore, primary stenting may offer additional benefits compared to balloon angioplasty in patients with acute myocardial infarction.

Objectives

To examine whether primary stenting compared to primary balloon angioplasty reduces clinical outcomes in patients with acute myocardial infarction.

Search strategy

We searched MEDLINE, EMBASE, Pascal, Index medicus and The Cochrane Controlled Trials Register (The Cochrane Library) from 1979 to March 2002.

Selection criteria

Randomised controlled trials of primary stenting or balloon angioplasty prior to the invasive procedure; intervention in native coronary arteries within 24 hours after onset of symptoms of myocardial infarction; report of death or reinfarction; and follow-up of at least 1 month. Trials were excluded when randomisation occurred after an invasive procedure and if they exclusively included patients with cardiogenic shock.

Data collection and analysis

Two reviewers independently selected and extracted data from identified trials. Outcomes included mortality, reinfarction, coronary artery bypass grafting, target vessel revascularization, need for vascular repair or blood transfusion. Peto odds ratios were calculated. To explore the stability of the overall treatment effect various sensitivity analyses were performed.

Main results

We included nine trials of 4433 participants. Odds ratios for mortality after stenting compared to balloon angioplasty at 30 days, 6 and 12 months were 1.16 (95% CI 0.78 to 1.73), 1.27 (95% CI 0.89 to 1.83), and 1.06 (95% CI 0.77 to 1.45). At 30 days, 6 and 12 months odds ratios for reinfarction after stenting compared to balloon angioplasty were 0.52 (95% CI 0.31 to 0.87), 0.67 (95% CI 0.45 to 1.00), and 0.67 (95% CI 0.45-0.98) and odds ratio for target vessel revascularization after stenting compared to balloon angioplasty were 0.45 (95% CI 0.34 to 0.60), 0.42 (95% CI 0.35 to 0.51), and 0.47 (95% CI 0.38 to 0.57). The odds ratio for post-interventional bleeding complications after stenting compared to balloon angioplasty was 1.34 (95% CI 0.95 to 1.88; test of heterogeneity $p > 0.1$).

Authors' conclusions

There is no evidence to suggest that primary stenting reduces mortality when compared to balloon angioplasty. Stenting seems to be associated with a reduced risk of reinfarction and target vessel revascularization, but potential confounding due to unbalanced post-interventional antithrombotic/anticoagulant therapies can not be ruled out on basis of this review.

SYNOPSIS

In people who have had a heart attack because of blocked heart arteries insertion of thin metal tubes (stents) were better than using small balloons to open the arteries up again.

Arteries can become clogged and narrowed with deposits of fat, cholesterol and other substances. This is called atherosclerosis and can cause heart attack. Two methods to open narrowed or clogged arteries in people who have had a recent heart attack are inserting a deflated small balloon in the artery and expand it to open the vessel (balloon angioplasty) or to insert a thin metal tube or sleeve (stent) into the artery to scaffold the artery open. This review compared these treatments and found both were equally effective at preventing death but using stents was better than balloon angioplasty because fewer arteries needed to be re-cleared and stents prevented more heart attacks than balloon angioplasty.

BACKGROUND

In patients with acute myocardial infarction balloon angioplasty reduces short-term death, non-fatal myocardial infarction and stroke when compared to thrombolytic reperfusion (Keeley 2003). However, the clinical efficacy of balloon angioplasty for acute myocardial infarction is limited by late restenosis in up to 50% of patients, and by recurrent myocardial infarction in 3 to 5 percent of patients (de Boer 1995; Nunn 1999; Stone 1995; Stone 1997). Therefore, primary stenting may offer additional benefits compared to balloon angioplasty in patients with acute myocardial infarction. A recent meta-analysis of clinical trials comparing primary stenting with balloon angioplasty in acute myocardial infarction found no difference in mortality and reinfarction rates (Zhu 2001). This systematic review, however, includes additional preliminary data from trials that have not been published in detail yet.

We conducted a meta-analysis based on published and unpublished trial data to investigate whether primary stenting compared to balloon angioplasty reduces mortality, recurrent events and the risk of bleeding in patients with acute myocardial infarction.

OBJECTIVES

To examine whether primary stenting compared to primary balloon angioplasty reduces clinical outcomes in patients with acute myocardial infarction.

CRITERIA FOR CONSIDERING STUDIES FOR THIS REVIEW

Types of studies

Randomised controlled trials.

Types of participants

People with acute myocardial infarction.

Types of intervention

Trials were included if they met the following criteria: randomisation to primary stenting or balloon angioplasty prior to the invasive procedure, intervention in native coronary arteries within 24 hours after onset of symptoms of acute myocardial infarction, report of death or reinfarction, and follow-up of at least one month. We excluded trials where patients were randomised after balloon angioplasty had already been performed and trials that exclusively included patients in cardiogenic shock.

Types of outcome measures

The main outcome of interest was mortality at 30 days, 6 and 12 months of follow-up. Other endpoints were reinfarction, coronary artery bypass grafting (CABG), target vessel revascularization, and a composite outcome of death and reinfarction at 30 days, 6 and 12 months after the intervention as well as procedure-related bleeding complications (defined as bleedings with need for vascular repair or blood transfusion, retroperitoneal, intracerebral or fatal bleedings).

SEARCH STRATEGY FOR IDENTIFICATION OF STUDIES

See: Heart Group search strategy

We searched MEDLINE, EMBASE, Pascal, Index medicus, The Cochrane Controlled Trials Register (*The Cochrane Library*) and abstracts from cardiology conferences from 1979 to March 2002 to identify all randomised controlled trials comparing primary stenting with balloon angioplasty in patients with acute myocardial infarction.

We used the following search terms:

Angioplasty-transluminal-percutaneous-coronary#,
Stents#,
Randomised-controlled-trials#,
Clinical-trials#,
Coronary-artery-dilatation#,
Transluminal-coronary-angioplasty#,

Random#.

In addition, we searched all references of relevant articles for additional trials and if necessary, contacted authors of identified trials to ask for additional information.

METHODS OF THE REVIEW

Selection of references to publications of interest

Two reviewers independently selected the relevant trials and resolved disagreement by consensus. The same reviewers extracted data from all trials that fulfilled inclusion criteria.

Assessment of trial quality

Two reviewers independently assessed the quality of each included trial and summarized the quality of each trial using a modified Jadad score (Jadad 1996). We rated the methodologic quality of the included trials based on the following items: 1) randomisation of participants, 2) blinding of patients, caregivers, and those assessing outcome 3) full description of withdrawals and drop outs. The scoring gives one point to each item if present. If randomisation is concealed, and if the method of double blinding is appropriate the study receives one additional point each, thus yielding a score with a range from 0 to 5 points. Agreement between the two reviewers was assessed by calculating proportions of specific agreement for positive and negative ratings (Cicchetti 1990). Disagreement between reviewers was resolved by consensus.

Examination of publication bias

We used a plot of standardized effect against precision to test for the presence of publication bias (funnel plot) (Figure 01) (Egger 1997).

Data aggregation and sensitivity analysis

We used RevMan Analyses statistical software to calculate Peto's odds ratios for the primary and secondary outcomes (Deeks 1998). To explore the stability of the overall treatment effect, we compared trials using different stent types, trials using different post-interventional antithrombotic / anticoagulant drug therapies, and trials with a crossover rate from balloon angioplasty to stenting below and above the median (cross-over rate of 15%). In addition, we compared trials reporting concealed randomisation with trials not reporting concealed randomisation, trials reporting blinded outcome assessment with trials not reporting blinded outcome assessment, and repeated analyses after excluding results of unpublished trials.

DESCRIPTION OF STUDIES

We identified 603 references of interest. Of the references with potential for inclusion 53 references to 47 studies were excluded (*See Table of Excluded studies*). 9 studies (10 references) met our inclusion criteria (GRAMI; Grines; Jaksch; PASTA; PRISAM; Scheller;

STENTIM-2; Stone; Suryapranata). Two citations were identified that referred to one trial and described outcomes and long-term follow-up results (Suryapranata). We did not include one trial where patients were randomised to provisional stenting or optimal balloon angioplasty because in this trial patients were randomised after balloon angioplasty had already been performed (Antoniucci 1998). Thus, nine trials with a total of 4433 patients were included in our meta-analysis (*See Characteristics of included studies tables*). Five of these trials explicitly excluded patients with cardiogenic shock. Two trials allowed for the inclusion of patients with cardiogenic shock: 8 out of 104 patients in the GRAMI trial and 6 out of 44 patients in the PSAAMI trial were in cardiogenic shock at inclusion (GRAMI; Scheller).

Routine use of abciximab was only foreseen in the study protocol of the CADILLAC trial (Stone). The CADILLAC-trial had a 2 by 2 factorial design and randomised patients to either balloon angioplasty alone, balloon angioplasty plus abciximab, stenting alone or stenting plus abciximab. In our primary analysis we compared all patients randomised to balloon angioplasty (with or without abciximab) with all patients randomised to stenting (with or without abciximab).

Palmaz-Schatz stents were used in three trials (Grines; PASTA; Suryapranata); one of them used a heparin-coated stent (Grines). Two trials used Wiktor stents (PRISAM; STENTIM-2). The remaining trials used various other types of stents (GRAMI; Jaksch; Scheller; Stone).

All trials used more aggressive post-interventional antithrombotic / anticoagulant therapies in patients assigned to stenting. Patients treated with stents were given aspirin and either ticlopidine, clopidogrel or warfarin, whereas patients treated with balloon angioplasty were generally only given aspirin. In the CADILLAC trial all patients randomised to stenting and approximately 50% of patients randomised to PTCA received either ticlopidine or clopidogrel (Stone).

Agreement on Quality Rating

There was complete agreement between both reviewers for concealment of treatment allocation, and full description of follow-up. For blinded outcome assessment, proportions of specific agreement were 0.80 for positive ratings and 0.92 for negative ratings.

METHODOLOGICAL QUALITY

Random allocation was concealed in 4 trials (Grines; Scheller; STENTIM-2; Stone) and possibly concealed in the remaining 5 trials (GRAMI; Jaksch; PASTA; PRISAM; Suryapranata). Blinded outcome assessment of clinical endpoints was reported only in three trials (Grines; Stone; Suryapranata). In three trials (Grines; Jaksch; Stone) description of follow-up and withdrawals was incomplete. See Table of Included studies.

RESULTS

Clinical Outcomes

Mortality (comparison 01, outcome 01, 02, 03).

Odds ratios for mortality at 30 days, 6 and 12 months after primary stenting compared to balloon angioplasty were 1.16 (95% Confidence Interval (CI) 0.78 to 1.73), 1.27 (95% CI 0.89 to 1.83), and 1.06 (95% CI 0.77 to 1.45). Although the point estimates indicated harm from primary stenting, they were not statistically significant as indicated by the 95% confidence intervals. There was no evidence of heterogeneity for all three estimates ($p > 0.1$).

Reinfarction (comparison 02, outcome 01, 02, 03).

Odds ratios for reinfarction after primary stenting compared to balloon angioplasty at 30 days, 6 and 12 months were 0.52 (95% CI 0.31 to 0.87), 0.67 (95% CI 0.45-1.00), and 0.67 (95% CI 0.45 to 0.98). There was some evidence of heterogeneity ($p > 0.1$) for reinfarction at 12 months, $p=0.08$.

Target vessel revascularisation (comparison 03, outcome 01, 02, 03).

Odds ratio for target vessel revascularization after primary stenting compared to balloon angioplasty at 30 days, 6 and 12 months were 0.45 (95% CI 0.34 to 0.60), 0.42 (95% CI 0.35 to 0.51) and 0.47 (95% CI 0.38 to 0.57).

Coronary artery bypass grafting

Odds ratios for coronary artery bypass grafting and the composite endpoint of reinfarction and death after primary stenting compared to balloon angioplasty were not statistically significant.

Post interventional bleeding

The odds ratio for post-interventional bleeding complications after primary stenting compared to balloon angioplasty was 1.34 (95% CI 0.95 to 1.88, test of heterogeneity $p > 0.1$).

Sensitivity Analyses

Stent type

In trials using Palmaz-Schatz stents odds ratios for 30 days, 6 and 12 months mortality after primary stenting compared to balloon angioplasty were 1.27 (95% CI 0.65 to 2.45), 1.21 (95% CI 0.66 to 2.25), and 1.35 (95% CI 0.79 to 2.31), and in trials using other types of stents 1.11 (95% CI 0.67 to 1.83), 1.01 (95% CI 0.66 to 1.52), and 0.97 (95% CI 0.66 to 1.44) (tests of heterogeneity for all comparisons $p > 0.1$).

Post intervention anti-thrombotics therapies

Since all trials used more potent post-interventional antithrombotic therapies in patients treated with stenting a sensitivity analysis for this pre-specified criteria was not possible. In order to control for a potential treatment interaction of abciximab, we repeated our analysis and excluded all patients treated with abciximab from the CADILLAC trial (Stone). When excluding patients treated with abciximab, the odds ratios for mortality after primary stenting compared to balloon angioplasty at 30 days, 6 and 12 months

follow-up were 1.20 (95% CI 0.80 to 1.80), 0.91 (95% CI 0.61 to 1.36) and 1.04 (95% CI 0.69 to 1.56) (tests of heterogeneity for all comparisons $p > 0.1$).

Cross over between treatment arms

In trials with lower crossover rates from balloon angioplasty to stenting (15%) odds ratios for 30 days, 6 and 12 months mortality after primary stenting compared to balloon angioplasty were 1.19 (95% CI 0.62 to 2.29), 1.21 (95% CI 0.66 to 2.21), and 1.35 (95% CI 0.79 to 2.31) as compared to 1.15 (95% CI 0.70 to 1.90), 1.01 (95% CI 0.66 to 1.55), and 0.97 (95% CI 0.66 to 1.44) in trials with crossover rates $> 15\%$ (tests of heterogeneity for all comparisons $p > 0.1$).

Concealment of treatment allocation

In trials reporting concealment of treatment allocation odds ratios for 30-days, 6 and 12 months mortality after primary stenting compared to balloon angioplasty were 1.72 (95% CI 1.13 to 2.63), 1.20 (95% CI 0.81 to 1.76) and 1.12 (95% CI 0.74 to 1.68). The corresponding odds ratios in trials not reporting concealment of treatment allocation were 0.60 (95% CI 0.28 to 1.28), 0.81 (95% CI 0.38 to 1.74), and 0.62 (95% CI 0.23 to 1.68) (tests for heterogeneity $p > 0.1$ for all comparisons with the exception of 12 months mortality in trials with concealed treatment allocation where $p = 0.09$).

Blinded outcome assessment

Odds ratios for 30-days, 6 and 12 months mortality after primary stenting compared to balloon angioplasty were 1.45 (95% CI 0.91 to 2.30), 1.15 (0.78 to 1.68), and 1.07 (95% CI 0.71 to 1.60) in trials reporting blinded outcome assessment. The corresponding odds ratios in trials not reporting blinded outcome assessment were 1.17 (95% CI 0.63 to 2.18), 0.95 (95% CI 0.43 to 2.11), and 0.79 (95% CI 0.27 to 2.30) (tests for heterogeneity $p > 0.1$ for all comparisons with the exception of 12 months mortality in trials with concealed treatment allocation where $p = 0.08$).

Excluding unpublished data

Odds ratios for 30-days and 6 months mortality for primary stenting compared to balloon angioplasty after exclusion of the two unpublished trials were 1.27 (95% CI 0.83 to 1.93) and 1.12 (95% CI 0.78 to 1.81) (tests of heterogeneity $p > 0.1$). Odds ratios for 30-days, 6 and 12 months reinfarctions for primary stenting compared to balloon angioplasty after exclusion of the two unpublished trials were 0.55 (95% CI 0.31 to 0.99), 0.71 (95% CI 0.47 to 1.09) and 0.67 (95% CI 0.45 to 0.99) (tests of heterogeneity $p > 0.1$).

Heterogeneity

There was no evidence of heterogeneity ($p > 0.1$) for all but one summary estimate (reinfarction at 12 months, $p=0.08$).

DISCUSSION

Our meta-analysis found no evidence that primary stenting in

acute myocardial infarction reduces overall mortality compared to balloon angioplasty. Contrary to the effect on mortality, primary stenting compared to balloon angioplasty reduces the risk of reinfarction and target vessel revascularization. At one year, on average 12 (95% CI 1 to 23) reinfarctions and 144 (95% CI 66 - 223) target vessel revascularizations are avoided per 1000 patients with acute myocardial infarction that are treated with primary stenting rather than balloon angioplasty.

This meta-analysis is based on a comprehensive literature search and the inclusion of additional unpublished data from individual trials. Although formal testing indicated no presence of publication bias, we cannot completely rule out such a bias. We explored heterogeneity between trials according to a priori defined criteria but lack of data precluded the detailed sensitivity analysis we envisaged. For the remaining criteria we found no evidence for heterogeneity. The test for heterogeneity has low power (Hardy 1998), particularly in meta-analyses of rare events (Sutton 2002), and this may be the main reason for our failure to detect heterogeneity.

This meta-analysis has some limitations. We were not able to obtain individual patient level data and had to rely on published and unpublished summary reports. The quality of included trials varied substantially. Only four trials reported concealed treatment allocation and only three reported blinded outcome assessment. Summary estimates in trials without reported concealed treatment allocation and without blinded outcome assessment indicated benefit from primary stenting, whereas both summary estimates in trials with higher quality indicated harm from routine stenting. Although our sensitivity analysis was inconclusive as 95% confidence intervals overlapped, this might be an indication that trial quality may have affected our summary estimates. By including trials of poorer quality into our analysis, we thus may underestimate the harmful effect of routine stenting on mortality in patients with acute myocardial infarction.

Cross-over rates from balloon angioplasty to stenting in some trials were substantial and ranged from 0 (PRISAM) to 36% (STENTIM-2) (*Characteristics of included studies table*). Sensitivity analysis comparing trials with lower (<15%) and higher (> 15%) crossover rates failed to reveal any difference in mortality. It is therefore unlikely that the crossover rates from balloon angioplasty to stenting in individual trials threaten the validity of our findings.

All trials used more aggressive post-interventional antithrombotic / anticoagulant therapies in patients assigned to stenting. The addition of an adenosine diphosphate (ADP) P2Y12 receptor antagonist (ticlopidine or clopidogrel) to aspirin following stenting has repeatedly been shown to offer greater protection from thrombotic complications than aspirin alone (Bertrand 1998; Leon 1998; Mehta 2001; Steinhubl 2002; Urban 1998). Thus, unbalanced cointervention might have introduced bias in favour of stenting and may explain the reduced odds of reinfarction and target vessel

revascularization in this group. However, it is not clear whether the addition of antithrombotic or anticoagulant drugs to aspirin is similarly beneficial in patients treated with balloon angioplasty without stent placement. In the TOSCA trial ticlopidine added to aspirin did not improve clinical outcomes in patients treated with balloon angioplasty (Berger 2001), but coumarins added to aspirin prevented acute and late complications after angioplasty in another trial (ten Berg 2000). Hence, further studies are needed to identify which antithrombotic strategy is most likely to be beneficial in stent recipients.

The external validity of our findings may be limited. Many trials were conducted in specialized high volume centres and some of them included highly pre-selected patients. Therefore, results from this analysis may not necessarily apply to patients treated in other centres or settings. Women and elderly patients were under-represented in the included trials, and thus the results of our meta-analysis can not easily be generalized to these groups.

Contrary to a previous meta-analysis we found a significant reduction in reinfarction rates in patients treated with primary stenting (Zhu 2001). This discrepant finding is mainly due to a difference in the inclusion of eligible trials. The previous systematic review included a large trial where there was no difference in reinfarction rate in the two treatment strategies (Antoniucci 1998). This trial did not meet our inclusion criteria because it did not compare primary stenting to balloon angioplasty per se, but to optimal balloon angioplasty. In addition, our analysis included data from a relatively large unpublished trial (Jaksch) where the reinfarction rate was lower in patients treated with stents.

Stent technology has developed considerably over the last few years. There is now a broad variety of stents with different physical and antithrombotic properties. Future trials comparing sirolimus-eluting stents to balloon angioplasty may show similar benefits of primary stenting in acute myocardial infarction as in chronic coronary artery disease (Morice 2002). However, so far these benefits have been limited to a reduction in restenosis and a reduced need for target vessel revascularizations, but not to a reduction of other end points like myocardial infarction or mortality. New stent types are more expensive and therefore, cost-effectiveness analyses and additional data on the long-term reliability will be important in justifying their use.

AUTHORS' CONCLUSIONS

Implications for practice

There is no evidence to suggest that primary stenting reduces mortality when compared to balloon angioplasty. Stenting seems to be associated with a reduced risk of reinfarction and target vessel revascularization, but potential confounding due to unbalanced post-interventional antithrombotic/anticoagulant therapies can not be ruled out on basis of this review.

Implications for research

Additional trials based on the use of modern sirolimus-eluting stents with extended follow-up periods and balanced antithrombotic therapies in both stent and balloon angioplasty arms are needed to better define the role of stents in the management of acute myocardial infarction.

POTENTIAL CONFLICT OF INTEREST

None known.

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*Indicates the major publication for the study

T A B L E S**Characteristics of included studies**

Study	GRAMI
Methods	RCT Mean follow-up 12 months.
Participants	Stent n=52 Angioplasty n=52 Mean Age 59 (10) 84% Male Criteria for the need of target vessel revascularization: Not specified.

Characteristics of included studies (Continued)

	Cross over from Balloon angioplasty to Stenting (%) = 25
Interventions	Stent type: Gianturco Roubin Differences in Post-interventional / Anti-thrombotic / Anti-coagulant therapy: Ticlopidine 500 mg/d for 4 weeks in stent-group only
Outcomes	30 day and 12 month revascularisation. 30 Day myocardial infarction and mortality. Numbers of successful dilation and numbers with post interventional bleeding.
Notes	Jadad score 3
Allocation concealment	B

Study	Grines
Methods	RCT Mean follow-up: 12 months
Participants	Stent n=452 Angioplasty n=433 Mean Age (SD) 60 (12) 75% Male Criteria for the need of target vessel revascularization: Clinical symptoms suggestive of ischemia and/or electrocardiographic changes during exercise testing. Cross over from Balloon angioplasty to Stenting (%) = 15
Interventions	Stent type: Heparin-coated Palmaz- Schatz Differences in Post-interventional / Anti-thrombotic / Anti-coagulant therapy: Ticlopidine in 93% of stent- and 88% of PTCA-group
Outcomes	30 day and 6 month revascularisation, myocardial infarction and 30 day, 6 month and 12 month mortality. Numbers of successful dilation and numbers with post interventional bleeding.
Notes	Jadad score 3
Allocation concealment	A

Study	Jaksch
Methods	RCT Mean follow up: 6 months.
Participants	Stent n=231 Angioplasty n=231 Mean Age (SD) 58 (12) 72% Male Criteria for the need of target vessel revascularization: Not specified. Cross over from Balloon angioplasty to Stenting (%) = 27
Interventions	Stent type: Various types Differences in Post-interventional / Anti-thrombotic/ Anti-coagulant therapy: Ticlopidine for 4 weeks in stent group only
Outcomes	30 day and 6 month revascularisation, myocardial infarction and mortality. Numbers of successful dilations.
Notes	Jadad score 1

Characteristics of included studies (Continued)

Allocation concealment B

Study	PASTA
Methods	RCT Mean follow-up 12 months.
Participants	Stent n=67 Angioplasty n=70 Mean Age (SD) 67 (11) 72 % Male Criteria for the need of target vessel revascularization: Not specified. Cross over from Balloon angioplasty to Stenting (%) = 10
Interventions	Stent type: Palmaz-Schatz. Differences in Post-interventional / Anti-thrombotic / Anti-coagulant therapy: Ticlopidine 200 mg for 4 weeks in stent-group only.
Outcomes	30 day, 6 and 12 month revascularisation, myocardial infarction and mortality. Numbers of successful dilation and numbers with post interventional bleeding
Notes	Jadad score 3
Allocation concealment	B

Study	PRISAM
Methods	RCT Mean follow-up: 6 months.
Participants	Stent n=110 Angioplasty n=112 Mean Age (SD): Data not available % Male: Data not available Criteria for the need of target vessel revascularization: Not specified. Cross over from Balloon angioplasty to Stenting (%) = 1
Interventions	Stent type Wiktor Differences in Post-interventional / Anti-thrombotic / Anti-coagulant therapy: No data
Outcomes	30 Day revascularisation and mortality.
Notes	Jadad score 1
Allocation concealment	B

Study	STENTIM-2
Methods	RCT Mean follow-up: 12 months.
Participants	Stent n=101 Angioplasty n=110 Mean Age (SD) 57 (12) 82 % Male Criteria for the need of target vessel revascularization: Not specified. Cross over from Balloon angioplasty to Stenting (%) = 36
Interventions	Stent type:

Characteristics of included studies (Continued)

	Wiktor GX
	Differences in Post-interventional Anti-thrombotic/Anti-coagulant therapy: Ticlopidine 500 mg/d for 4 weeks in stent-group only
Outcomes	30 day, 6 and 12 month revascularisation, myocardial infarction and mortality. Numbers of successful dilation and numbers with post interventional bleeding.
Notes	Jadad score 4
Allocation concealment	A

Study	Scheller
Methods	RCT Mean follow-up 24 months.
Participants	Stent n=44 Angioplasty n=44 Mean Age (SD) 61 (10) 76 % Male Criteria for the need of target vessel revascularization: Not specified. Cross over from Balloon angioplasty to Stenting (%) = 27
Interventions	Stent type: Tensum III Differences in Post-interventional / Anti-thrombotic / Anti-coagulant therapy: Ticlopidine 500 mg/d for 4 weeks in stent-group only, abciximab in 48% of patients in both groups.
Outcomes	30 day and 12 month revascularisation, myocardial infarction and mortality. Numbers of successful dilation and numbers with post interventional bleeding.
Notes	Jadad score 4
Allocation concealment	A

Study	Stone
Methods	RCT Mean follow-up 12 months
Participants	Stent n=1036 Angioplasty n=1046 Mean Age 60 73 % Male Criteria for the need of target vessel revascularization: Evidence of ischemia during functional testing or angina. Cross over from Balloon angioplasty to Stenting (%) = 16
Interventions	Stent type: Multi- Link and Multi Link Duet Differences in Post-interventional / Anti-thrombotic / Anti-coagulant therapy: Ticlopidine 250 mg bid or clopidogrel 75 mg/d for 4 weeks in stent-group only Abciximab for 50% of patients in both groups, approximately 50% of patients ticlopidine or clopidogrel.
Outcomes	30 day, 6 and 12 month revascularisation, myocardial infarction and mortality. Numbers of successful dilation and numbers with post interventional bleeding.
Notes	Jadad score 3
Allocation concealment	A

Characteristics of included studies (Continued)

Study	Suryapranata
Methods	RCT Mean follow-up 12 months
Participants	Stent n=112 Angioplasty n=115 Mean Age (SD) 58 (11) 84% Male Criteria for the need of target vessel revascularization: Electrocardiographic or scintigraphic evidence of ischemia at rest or on exercise testing. Cross over from Balloon angioplasty to Stenting (%) = 13
Interventions	Stent type: Palmaz-Schatz Differences in Post-interventional / Anti-thrombotic / Anti-coagulant therapy: Warfarin 3 months and ticlopidine 250 mg/d for 2 weeks in stent-group only.
Outcomes	30 day, 6 and 12 month revascularisation, myocardial infarction and mortality. Numbers of successful dilation and numbers with post interventional bleeding.
Notes	Jadad score 4
Allocation concealment	B

Characteristics of excluded studies

ADVANCE	Provisional stenting
BENESTENT	Intervention not within 24 hours after onset of symptoms of acute myocardial infarction
BET	Other
BOSS	Intervention not within 24 hours after onset of symptoms of acute myocardial infarction
Brener	Intervention not done on native coronary vessels
Briguori	Not randomised
Cura	Subgroup analysis of included trials
DESTINI	Intervention not within 24 hours after onset of symptoms of acute myocardial infarction (Di Mario 2000) AND Subgroup analysis of included trials (Moussa 2002)
Doucet	Intervention not within 24 hours after onset of symptoms of acute myocardial infarction
EPISTENT	Subgroup analysis of included trials (Marso 1999). Intervention not within 24 hours after onset of symptoms of acute myocardial infarction (The Epistent investigators 1998)
Eeckhout	Intervention not within 24 hours after onset of symptoms of acute myocardial infarction
Elezi	Not randomised
FRESCO	Provisional stenting, participants randomised after balloon angioplasty.
FROST	Provisional stenting
Fischman	Intervention not within 24 hours after onset of symptoms of acute myocardial infarction
GISSOC	Provisional stenting
Gruberg	No native vessels
Hancock	Provisional stenting
ISAR-SMART	Subgroup analysis of included trials AND Intervention not within 24 hours after onset of symptoms of acute myocardial infarction

Characteristics of excluded studies (Continued)

Kastrati	Stent versus stent
Katz	Not randomised
Koning	No useful outcome data
Kovar	Other
Lincoff	Intervention not within 24 hours after onset of symptoms of acute myocardial infarction
Mehilli	Stent versus stent
Miketic(a)	Stent versus stent
Miketic(b)	Other
Mori	Not randomised
Niazi	Intervention not within 24 hours after onset of symptoms of acute myocardial infarction
OCBAS	Provisional stenting
OPUS-1	Intervention not within 24 hours after onset of symptoms of acute myocardial infarction
Prieto	Provisional stenting
SARECCO	Provisional stenting
SICCO	Provisional stenting
SISCA	Intervention not within 24 hours after onset of symptoms of acute myocardial infarction
START	Intervention not within 24 hours after onset of symptoms of acute myocardial infarction
STOP	Provisional stenting
STRESS I	Intervention not within 24 hours after onset of symptoms of acute myocardial infarction
Sasao	Not randomised
Savage	Intervention not done on native coronary vessels
TOSCA	Intervention not within 24 hours after onset of symptoms of acute myocardial infarction
Topol	Intervention not within 24 hours after onset of symptoms of acute myocardial infarction
Versaci	Intervention not within 24 hours after onset of symptoms of acute myocardial infarction
WIDEST	Intervention not within 24 hours after onset of symptoms of acute myocardial infarction
Waksman	Not randomised
Witkowski 2000	Intervention not within 24 hours after onset of symptoms of acute myocardial infarction
Wong	Intervention not done on native coronary vessels

GRAPHS

Comparison 01. Mortality

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 30 Day	9	4428	Peto Odds Ratio 95% CI	1.16 [0.78, 1.73]
02 6 months	6	4014	Peto Odds Ratio 95% CI	1.27 [0.89, 1.83]
03 12 Months	6	3640	Peto Odds Ratio 95% CI	1.06 [0.77, 1.45]

Comparison 02. Myocardial Infarction

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 30 day	8	4206	Peto Odds Ratio 95% CI	0.52 [0.31, 0.87]
02 6 Month	6	4014	Peto Odds Ratio 95% CI	0.67 [0.45, 1.00]
03 12 Month	6	3640	Peto Odds Ratio 95% CI	0.67 [0.45, 0.98]

Comparison 03. Revascularisation

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 30 Day	9	4428	Peto Odds Ratio 95% CI	0.45 [0.34, 0.60]
02 6 Month	6	4014	Peto Odds Ratio 95% CI	0.42 [0.35, 0.51]
03 12 Month	6	2849	Peto Odds Ratio 95% CI	0.47 [0.38, 0.57]
04 Successful dilation	8	4206	Peto Odds Ratio 95% CI	0.96 [0.71, 1.29]

Comparison 04. Adverse events

Outcome title	No. of studies	No. of participants	Statistical method	Effect size
01 Bleeding	7	3744	Peto Odds Ratio 95% CI	1.34 [0.95, 1.88]

INDEX TERMS

Medical Subject Headings (MeSH)

Angioplasty, Transluminal, Percutaneous Coronary; Myocardial Infarction [mortality]; Randomized Controlled Trials; Stents; Thrombolytic Therapy

Medical MeSH check words

Humans

COVER SHEET

Title	Primary stenting versus primary balloon angioplasty for treating acute myocardial infarction
Authors	Nordmann AJ, Bucher H, Hengstler P, Harr T, Young J
Contribution of author(s)	AJ Nordmann analysed the data and wrote the manuscript. P Hengstler and T Harr collected the data. J Young gave statistical advice and helped writing the manuscript. HC Bucher designed the study and helped writing the manuscript.
Issue protocol first published	/
Review first published	2005/2
Date of most recent amendment	14 August 2005
Date of most recent SUBSTANTIVE amendment	01 February 2005
What's New	Minor update Issue 4 2005, August The data for the Grines study and the Jaksch study for 6 month mortality were transposed. This error is now corrected.

Grines CL, Cox DA, Stone GW et al. 1999. Coronary angioplasty with or without stent implantation for acute myocardial infarction. Stent Primary Angioplasty in Myocardial Infarction Study Group. *New England Journal of Medicine*. 1999;341;26; 1949-56.
Jaksch R, Niehus R, Knobloch W, Schiele T. PTCA versus stenting in acute myocardial infarction. *European Heart Journal*. 1998;19;239;1341.

Date new studies sought but none found Information not supplied by author

Date new studies found but not yet included/excluded Information not supplied by author

Date new studies found and included/excluded Information not supplied by author

Date authors' conclusions section amended Information not supplied by author

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GRAPHS AND OTHER TABLES

Fig. 1.

Review: Primary stenting versus primary balloon angioplasty for the treatment of acute myocardial infarction
Comparison: 01 Mortality
Outcome: 01 30 Day

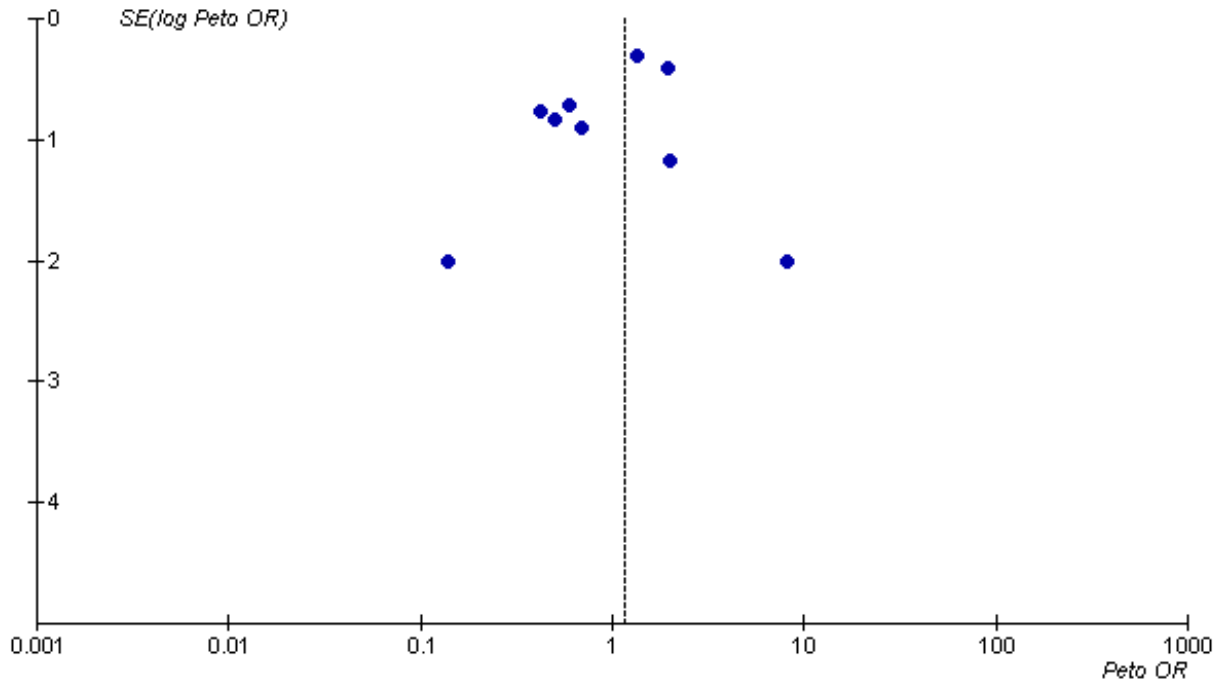


Fig. 2. Comparison 01. Mortality

01.01 30 Day

Review: Primary stenting versus primary balloon angioplasty for treating acute myocardial infarction

Comparison: 01 Mortality

Outcome: 01 30 Day

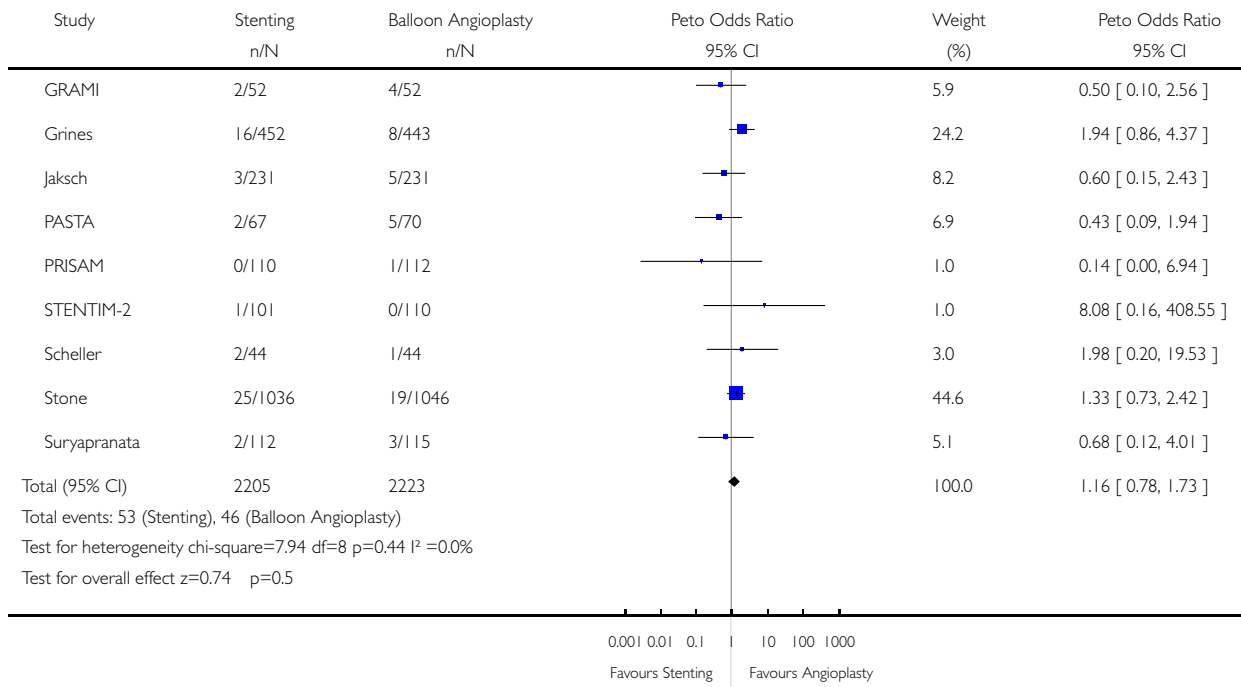


Fig. 3. Comparison 01. Mortality

01.02 6 months

Review: Primary stenting versus primary balloon angioplasty for treating acute myocardial infarction

Comparison: 01 Mortality

Outcome: 02 6 months

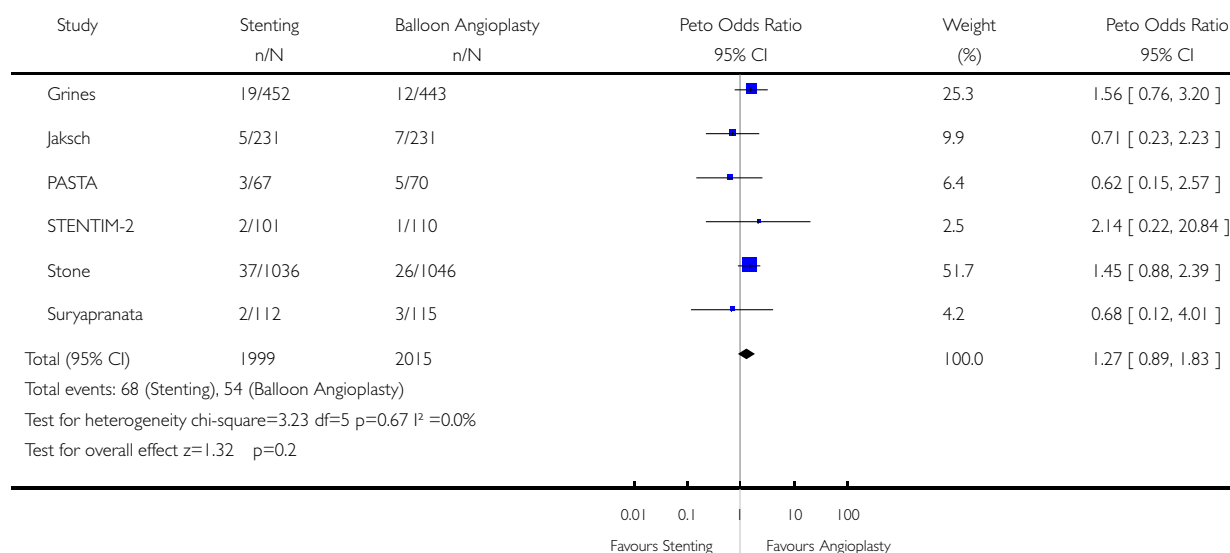


Fig. 4. Comparison 01. Mortality

01.03 12 Months

Review: Primary stenting versus primary balloon angioplasty for treating acute myocardial infarction

Comparison: 01 Mortality

Outcome: 03 12 Months

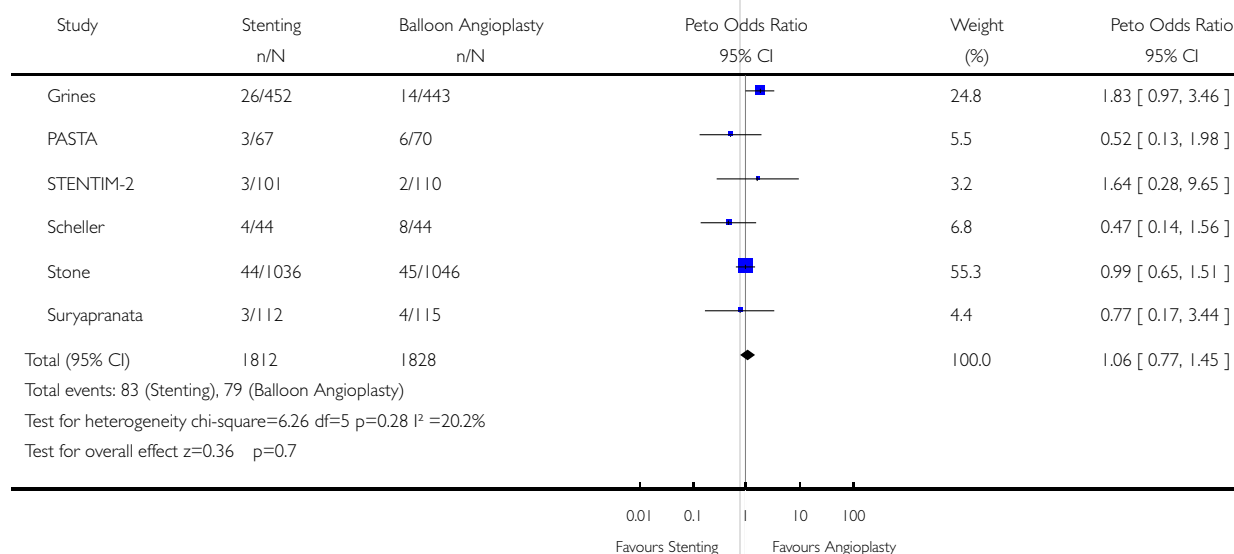


Fig. 5. Comparison 02. Myocardial Infarction

02.01 30 day

Review: Primary stenting versus primary balloon angioplasty for treating acute myocardial infarction

Comparison: 02 Myocardial Infarction

Outcome: 01 30 day

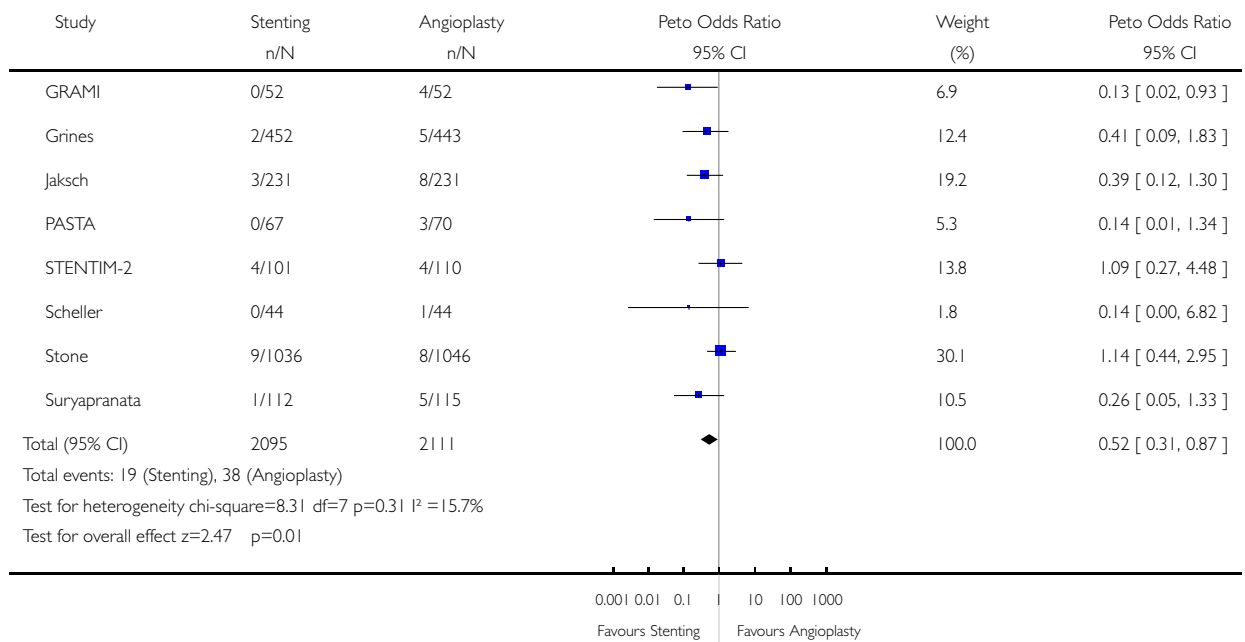


Fig. 6. Comparison 02. Myocardial Infarction

02.02 6 Month

Review: Primary stenting versus primary balloon angioplasty for treating acute myocardial infarction

Comparison: 02 Myocardial Infarction

Outcome: 02 6 Month

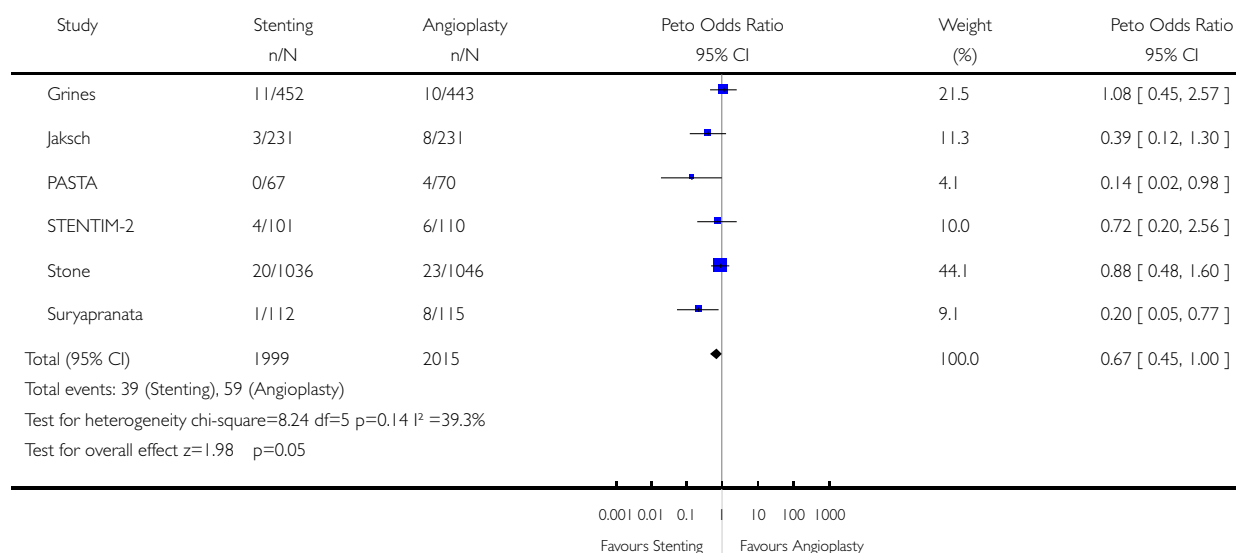


Fig. 7. Comparison 02. Myocardial Infarction

02.03 12 Month

Review: Primary stenting versus primary balloon angioplasty for treating acute myocardial infarction

Comparison: 02 Myocardial Infarction

Outcome: 03 12 Month

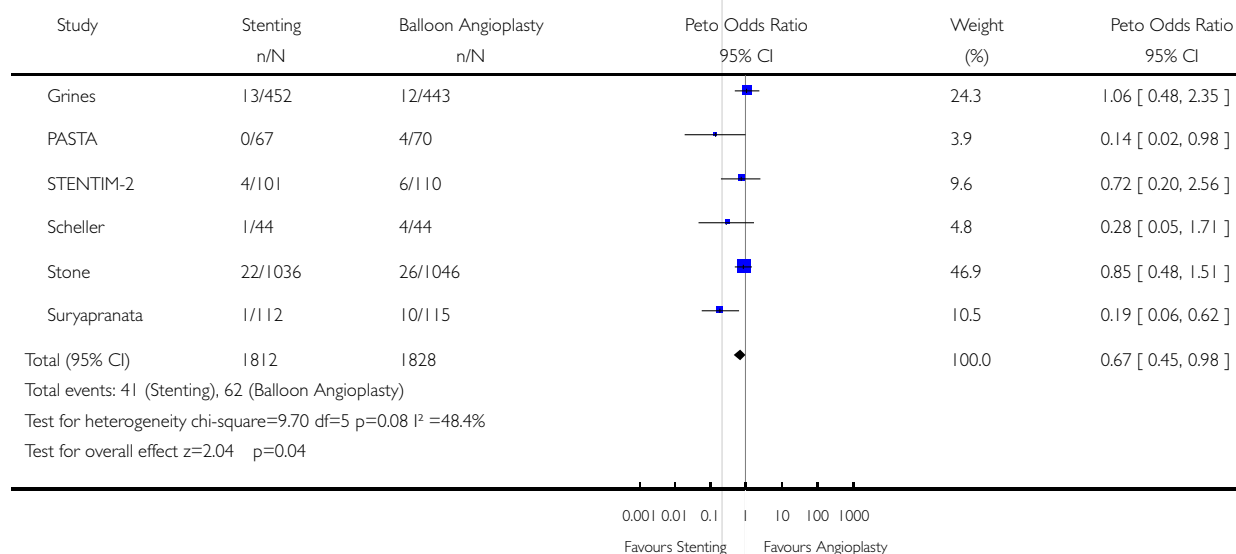


Fig. 8. Comparison 03. Revascularisation

03.01 30 Day

Review: Primary stenting versus primary balloon angioplasty for treating acute myocardial infarction

Comparison: 03 Revascularisation

Outcome: 01 30 Day

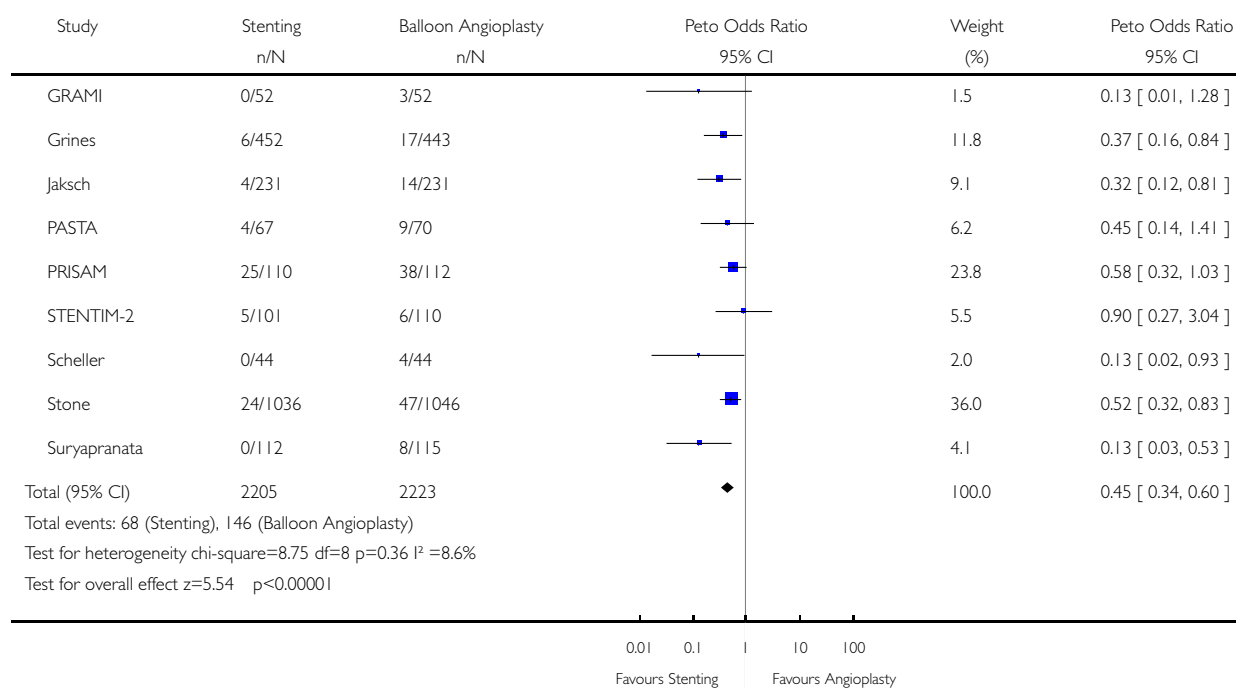


Fig. 9. Comparison 03. Revascularisation

03.02 6 Month

Review: Primary stenting versus primary balloon angioplasty for treating acute myocardial infarction

Comparison: 03 Revascularisation

Outcome: 02 6 Month

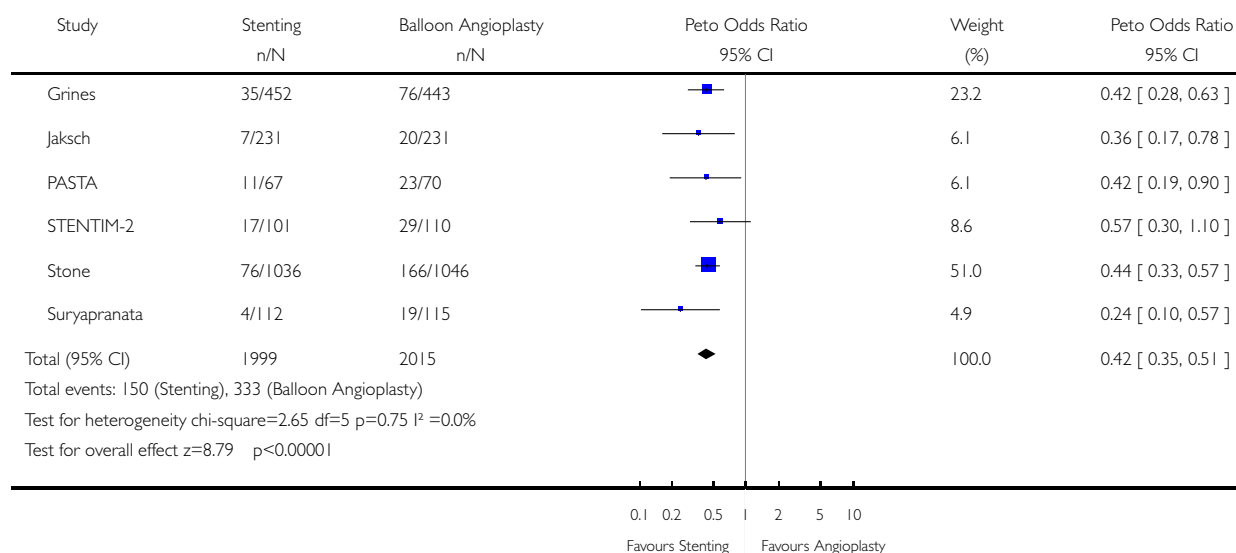


Fig. 10. Comparison 03. Revascularisation

03.03 12 Month

Review: Primary stenting versus primary balloon angioplasty for treating acute myocardial infarction

Comparison: 03 Revascularisation

Outcome: 03 12 Month

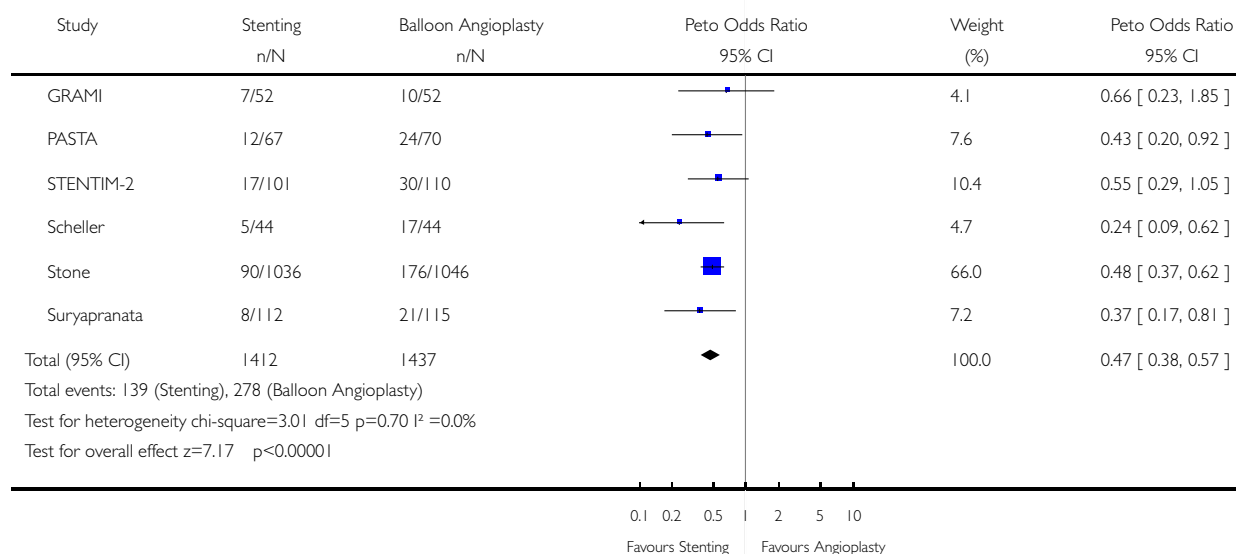


Fig. 11. Comparison 03. Revascularisation

03.04 Successful dilation

Review: Primary stenting versus primary balloon angioplasty for treating acute myocardial infarction

Comparison: 03 Revascularisation

Outcome: 04 Successful dilation

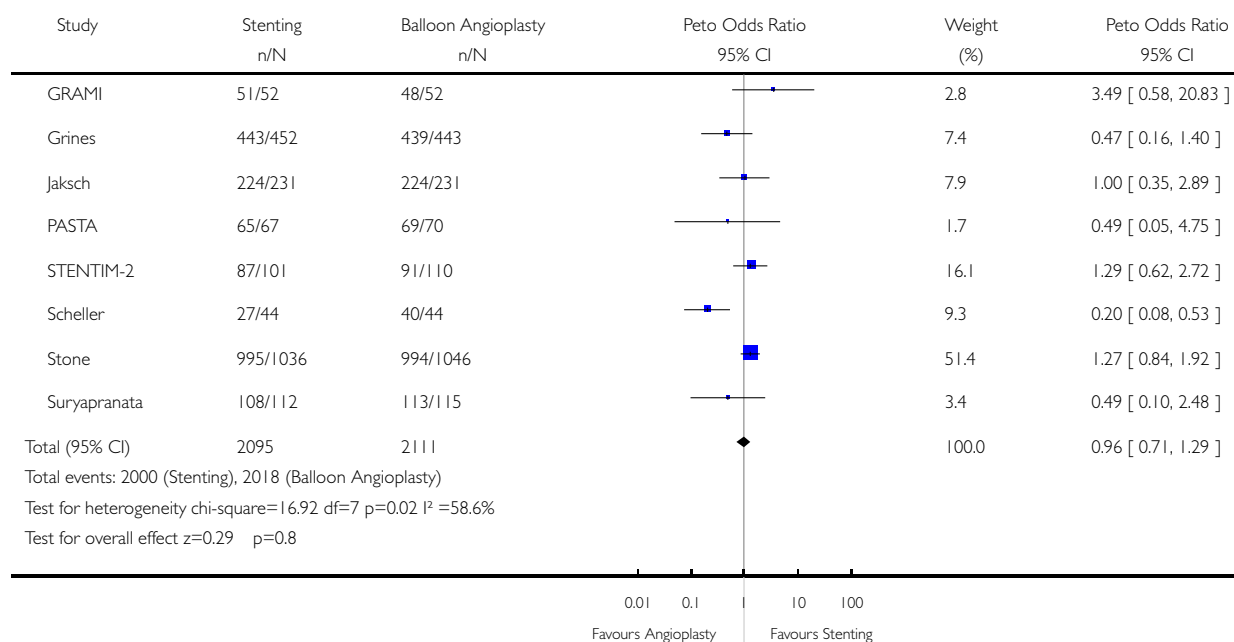


Fig. 12. Comparison 04. Adverse events

04.01 Bleeding

Review: Primary stenting versus primary balloon angioplasty for treating acute myocardial infarction

Comparison: 04 Adverse events

Outcome: 01 Bleeding

