Author's response to reviews

**Title:** Drug-eluting stents or coronary artery bypass grafting for unprotected left main coronary artery disease: a meta-analysis of four randomized trials and seventeen observational studies

**Authors:**

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**Version:** 2 **Date:** 27 March 2013

**Author's response to reviews:** see over
Dear Profs. Doug Altman, Curt Furberg, Jeremy Grimshaw and Peter Rothwell:

Please find attached a revised version of our manuscript “Drug-eluting stents or coronary artery bypass grafting for unprotected left main coronary artery disease: a meta-analysis of four randomized trials and seventeen observational studies (MS: 1021213778305014)”, which we would like to resubmit for publication in Trials.

Your comments and those of the reviewers were highly insightful and enabled us to greatly improve the quality of our manuscript. In the following pages, there are our point-by-point responses to each of the comments of the reviewers as well as your own comments.

We hope that the revisions in the manuscript and our accompanying responses will be sufficient to make our manuscript suitable for publication in Trials.

We shall look forward to hearing from you at your earliest convenience.

Yours sincerely,

Rui-Xing Yin
Responses to the comments of Reviewer

Reviewer number: 1
Reviewer: Meng-Hua Chen
Reviewer's report:
Dear Prof. Meng-Hua Chen:

Thank you for your kind instructive comments and suggestions.

Major comments

The manuscript by Li and colleagues evaluates the safety and efficacy of drug-eluting stents (DES) or coronary artery bypass grafting (CABG) for unprotected left main coronary artery disease (ULMCAD). There are 4 RCTs and 17 non-randomized studies including 8413 patients. This meta-analysis showed that DES has higher safety but higher revascularization than CABG in patients with ULMCAD in the 5 years after intervention. The design and methods of the analysis are quite adequate and the data obtained may be of interest to the investigators on this field.

Some suggestions:
1. “Abstract”: The results in the abstract are not clear, thus, the conclusions are also poor. “Therefore, DES may be a better alternative for ULMCAD” ought to delete.

Response: Yes, it has been deleted

2. There are too many abbreviations in the text.

Response: Yes, it has been corrected

3. “Conclusion” in the text: need to edit.

Response: Yes, it has been reedit

4. There are some typographical errors in the text.

Response: Yes, it has been corrected
5. All parts of the manuscript ought to be edited according to the journal format.

**Response:** Yes, we have done

**Reviewer number:** 2  
**Reviewer:** Shangling Pan  
**Reviewer's report:**
Dear Prof. Shangling Pan:

Thank you for your kind instructive comments and suggestions.

1. The manuscript needs page numbers.

**Response:** Yes, it has been added

2. There are some typographical errors throughout the text.

**Response:** Yes, it has been corrected

3. All parts of the manuscript ought to be edited according to the journal format.

**Response:** Yes, we have done

Thank you very much!

Sincerely yours,

Rui-Xing Yin
Drug-eluting stents or coronary artery bypass grafting for unprotected left main coronary artery disease: a meta-analysis of four randomized trials and seventeen observational studies

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Abstract

**Background:** The clinical application of drug-eluting stents (DES) or coronary artery bypass grafting (CABG) for unprotected left main coronary artery disease (ULMCAD) is still controversial. The purpose of this meta-analysis was to compare the safety and efficacy between DES and CABG for ULMCAD.

**Methods:** Databases of MEDLINE, EMBASE and the Cochrane Library were systematically searched.

**Results:** Twenty-one studies with 8413 patients were included in this meta-analysis. The risk was lower in DES than in CABG groups at the early outcomes of death ([risk ratio (RR): 0.49, 95% confidence interval (CI): 0.30–0.78]), cerebrovascular events (RR: 0.19, 95% CI: 0.08–0.45) and composite endpoint (RR: 0.53, 95% CI: 0.40–0.70); death of 2-years (RR: 0.81, 95% CI: 0.66–0.99), 4-years (RR: 0.69, 95% CI: 0.53–0.90), 5-years (OR: 0.76, 95% CI: 0.61–0.95) and their total effect (RR: 0.79, 95% CI: 0.71–0.87); composite endpoint of 1-year (RR: 0.69, 95% CI: 0.58–0.83), 4-years (RR: 0.69, 95% CI: 0.53–0.88), 5-years (RR: 0.74, 95% CI: 0.59–0.92) and their total effect (RR: 0.78, 95% CI: 0.71–0.85). There were no significant difference in the risk for the early outcomes of myocardial infarction MI (RR: 0.97, 95% CI: 0.68–1.38), death of 1-years (OR: 0.81, 95% CI: 0.57–1.15) and 3-years (OR: 0.85, 95% CI: 0.69–1.04), composite endpoint of 2-years (RR: 0.88, 95% CI: 0.72–1.09) and 3-years (RR: 0.87, 95% CI: 0.73–1.04). Nonetheless, there was a lower risk for revascularization associated with CABG from 1- to 5-years and their total effect (RR: 3.77, 95% CI: 3.35–4.26). There was no difference in death, myocardial infarction MI, cerebrovascular events or revascularization in 1-year between RCT and observational groups.
**Conclusions:** Our meta-analysis indicates that DES has higher safety but higher revascularization than CABG in patients with ULMCAD in the 5 years after intervention. Therefore, DES may be a better alternative for ULMCAD.

**Key Words:** Drug-eluting stents  coronary artery bypass grafting  unprotected left main coronary artery disease  meta-analysis
Background

As we all know, To our knowledge, approximately 4–9% of patients undergoing diagnostic coronary angiography [1] are found unprotected left main stenosis which has been shown to portend high mortality [2, 3], and percutaneous coronary intervention (PCI) involving drug-eluting stents (DES) is increasingly used to treat unprotected left main coronary artery disease (ULMCAD) in recent years, although coronary artery bypass grafting (CABG) has been the treatment of choice historically [4, 5]. One of the main limitations of PCI for ULMCAD is in-stent restenosis and the need for repeat revascularization, especially in bare-metal stents [6, 7], therefore the European Society of Cardiology guidelines and American Heart Association guidelines suggest that PCI for ULMCAD should be only reserved for those who are poor candidates for CABG [8]. However, several meta-analyses [9-12] of DES versus CABG for in ULMCAD showed that the results are controversial, and many new clinical trials [13-16] have been published in recent years. Therefore, it is necessary to conduct a new meta-analysis and to assess the safety and efficacy of DES and CABG among patients with ULMCAD in the early outcomes (≤ 30 days or in-hospital early), 1- to 5-year follow-up, and it is also necessary to compare the difference in safety and efficacy of DES and CABG between RCT and observational groups.

Methods

Search Strategy

The data of this meta-analysis were obtained from the following sources: MEDLINE via PubMed (from 1950 to June 2012), EMBASE (June 1980 to June 2012) and the Cochrane
Library database (Cochrane Central Register of Controlled Trials, from 1991 to June 2012). The following key words were used: “coronary artery bypass,” “drug-eluting stent,” “paclitaxel-eluting stent”, “sirolimus-eluting stent”, and “left main coronary artery”. The above search strategy described was used to obtain titles and abstracts of studies that may have been relevant to this review. The titles and abstracts were screened independently by two authors (Qing Li and Zhi Zhang), who discarded studies that were not applicable. When multiple reports from the same patients were found, only the study with the most complete data set was included in the meta-analysis. But duplicate patients of different articles that have different types of data of outcomes were included both. Any disagreements were arbitrated by discussion with the third reviewer (Rui-Xing Yin).

**Included and excluded studies**

Studies were included in this meta-analysis if they met the following criteria: (1) clinical trials published in peer-reviewed journals with full available text in English; (2) clinical trials comparing CABG with DES for LMCAD; (3) reporting at least one relevant clinical endpoint including revascularization, myocardial infarction (MI), cerebrovascular events, death or the composite endpoint (death, myocardial infarction MI, or cerebrovascular events); and (4) follow-up duration ≥ 30 days. Excluded studies: (1) studies using only bare-metal stents or mixtures of bare-metal stents and DES but not comparing DES with CABG separately in the PCI group were excluded from this study; (2) studies in which it was not possible to extract data from the published results as well as those studies that did not report appropriate outcomes were also excluded.
Types of outcome measures

The safety endpoints of this meta-analysis were death, cerebrovascular events, myocardial infarction MI and the composite endpoint of death, myocardial infarction MI or cerebrovascular events. The efficacy endpoint was revascularization. Death was defined as death from any cause. Myocardial infarction MI included Q-wave MI and non-Q-wave myocardial infarction MI. Cerebrovascular events included ischemic attacks, stroke, and reversible ischemic neurological deficits. Revascularization was the need for repeated CABG or PCI.

Data extraction and management

Two investigators independently extracted data according to the author details and the following information was extracted from each study: methodological quality, first author, year of publication, number of patients in each group (CABG or DES), baseline characteristics, interventions, outcomes and duration of follow-up. Otherwise, probabilities of death or other endpoints were estimated from published Kaplan-Meier survival curves. Discrepancies were resolved by discussion. When repeated publications of the same trial were identified, data were extracted from the repeated publications and reported as a single trial.

Quality of the evidence recommendations methodology

The evidence recommendations in our meta-analysis have been graded according to the
Grading of Recommendations Assessment Development and Evaluation (GRADE) system by Grade software [17]. The quality of the evidence has been classified as three levels: high (☉☉☉☉☉), moderate (☉☉☉☉☉), low (☉☉☉☉☉) or very low (☉☉☉☉☉).

Statistical analysis

We carried out statistical analysis by the Review Manager software 5.1.0 (updated in March 2011 by the Cochrane Collaboration). For dichotomous outcomes of individual studies were expressed as risk ratio (RR) with 95% confidence intervals (CI). The pooled effects were calculated using fixed-effects models when there was no significant heterogeneity but the random effects model was analyzed to ensure robustness of the model chosen and susceptibility to outliers, or using random effects models when there was significant heterogeneity but the fixed effects model was analyzed to ensure robustness of the model chosen and susceptibility to outliers. The point estimate of the RR was considered statistically significant at the 2-tailed \( P \leq 0.05 \) level. Heterogeneity was analyzed using a chi-square test on N-1 degrees of freedom [18]. \( P \) values of 25%, 50% and 75% correspond to low, medium and high levels of heterogeneity. Subgroup analysis was used to explore possible sources of heterogeneity (e.g. duration of follow-up, type of outcomes and study quality). Sensitivity analyses were performed omitting a single study at a time or analyzed another model chosen. If enough studies were identified, funnel plots were to be used to investigate reporting biases [19]. The baseline characteristics were analyzed with chi-square test for categorical variables.
**Results**

**Characteristics of included studies**

Twenty-one studies met our criteria for inclusion in the meta-analysis (Figure 1). Four studies were randomized controlled trials [13, 15, 20, 21] and seventeen studies were observational studies [4-8, 14, 16, 22-36]. Several studies might be duplicate patients but they had different types data of outcomes, e.g. one study [20] had the earth outcomes but another some [13] did had not. A total of 8413 patients were included in the analysis. There were 4731 patients who received CABG and 3682 patients who received PCI with DES. The main characteristics of the each studies are shown in Table 1.

**Baseline characteristics of the trials**

The baseline clinical characteristics between the PCI and CABG groups are detailed in Table 2. There were no significant differences in the prevalence of hypertension, current smoking, diabetes mellitus, previous stroke, chronic renal failure between the two groups ($P > 0.05$ for all). The proportions of females and previous PCI were lower but the prevalence of hyperlipidemia, previous myocardial infarction MI and right coronary artery disease were higher in CABG than in PCI groups ($P < 0.05$ for all).

**Clinical Outcomes**

**The early outcomes (≤ 30 days or in-hospital early):** The early outcomes (≤ 30 days or in-hospital early) of DES and CABG groups and the pooled effects are shown in Figure 2. Pooled effects indicated that CABG group had higher risk of death (RR: 0.49, 95% CI:
cerebrovascular events (RR: 0.19, 95% CI: 0.08–0.45, \( P = 0.0002 \)) and composite endpoint (RR: 0.53, 95% CI: 0.40–0.70, \( P < 0.00001 \)) than PCI group. There was no difference in myocardial infarction MI (RR: 0.97, 95% CI: 0.68–1.38, \( P = 0.86 \)) between CABG and PCI groups.

**Death from 1- to 5-years:** Death from 1- to 5-years between CABG and PCI groups is shown in Figure 3. Pooled effects showed that CABG group had higher dead risk than PCI group in 2-years (RR: 0.81, 95% CI: 0.66–0.99, \( P = 0.04 \)), 4-years (RR: 0.69, 95% CI: 0.53–0.90, \( P = 0.007 \)), 5-years (OR: 0.76, 95% CI: 0.61–0.95, \( P = 0.02 \)) and total pooled outcome (RR: 0.79, 95% CI: 0.71–0.87, \( P < 0.00001 \)). There was no difference in 1-year dead (RR: 0.80, 95% CI: 0.63–1.02, \( P = 0.07 \)) and 3-year dead (OR: 0.85, 95% CI: 0.69–1.04, \( P = 0.11 \)) between CABG and PCI groups.

**Composite endpoint from 1- to 5-years:** The outcomes of composite endpoint of death, myocardial infarction MI, cerebrovascular events from 1- to 5-years between CABG and PCI groups are detailed in Figure 4. Pooled effects showed that CABG group had higher composite endpoint risk than PCI group in 1-year (RR: 0.69, 95% CI: 0.58–0.83, \( P = 0.0001 \)), 4-years (RR: 0.69, 95% CI: 0.53–0.88, \( P = 0.003 \)), 5-years (RR: 0.74, 95% CI: 0.59–0.92, \( P = 0.007 \)) and total pooled outcome (RR: 0.78, 95% CI: 0.71–0.85, \( P < 0.00001 \)). There was no difference in composite endpoint in 2-years (RR: 0.88, 95% CI: 0.72–1.09, \( P = 0.24 \)) and 3-years (RR: 0.87, 95% CI: 0.73–1.04, \( P = 0.14 \)) between CABG and PCI groups.

**Revascularization from 1- to 5-years:** The outcomes of revascularization from 1- to 5-years between PCI and CABG groups are shown in Figure 5. Pooled effects showed that PCI group had higher revascularization risk than CABG group in 1-year (RR:3.38, 95% CI:
2.75–4.15, *P* < 0.00001), 2-year (RR: 3.81, 95% CI: 2.93–4.95, *P* < 0.00001), 3-year (RR: 4.42, 95% CI: 3.40–5.75, *P* < 0.00001), 4-year (RR: 3.22, 95% CI: 2.28–4.54, *P* < 0.00001), and 5-years (RR: 4.43, 95% CI: 3.08–6.37, *P* < 0.00001) and total pooled outcome (RR: 3.77, 95% CI: 3.35–4.26, *P* < 0.00001).

**Outcomes of 1-year between RCT and observational groups:** The outcomes of RCT and observational groups in 1-year are shown in Figures 6–9. Pooled effects showed that there were no different outcomes between RCT and observational groups in death, myocardial infarction MI, cerebrovascular events or revascularization. There were also no differences in both of death and myocardial infarction MI for CABG and PCI in both RCT and observational groups (*P* > 0.05 for each). PCI group had higher revascularization risk than CABG group (*P* < 0.00001), whereas CABG group had higher cerebrovascular events risk than PCI group (*P* = 0.001) in the two groups.

**Sensitivity analysis**

Sensitivity analyses were performed to assess the contribution of each study to the pooled estimate and by excluding individual studies one at a time and recalculating the pooled RR estimates for the remaining studies. Eliminating the studies with more than 300 patients or fewer than 100 patients in each group did not substantially change the pooled point estimate. Moreover, analysis of four RCTs separately did not also substantively alter the overall result of our analysis. Last but not least, performing transition of model also did not substantially change the pooled point estimate.
Discussion

The results of the present meta-analysis showed demonstrate that PCI with DES for ULMCAD may be a better alternative to CABG, because the early subtotal outcomes of death, cerebrovascular events and composite endpoint; death of 2-, 4- and 5-years and composite endpoint of 1-, 4- and 5-years, combined with their total outcomes, were lower risk in PCI than in CABG groups. There was no difference in the risk for the early outcomes of myocardial infarction MI, death of 3-years and composite endpoint of 2- and 3-years. Nevertheless, there was a lower risk for revascularization associated with CABG. There was no significant difference in death, myocardial infarction MI, cerebrovascular events or revascularization between RCT and observational groups.

Recently, three meta-analyses [10, 12, 37] including RCTs and observational studies showed no significant differences in the safety between CABG and DES and superiority of CABG to DES for repeated revascularization in patients with ULMCAD. A meta-analysis including 3,773 patients and following up to 3 years believed that PCI was emerging as an acceptable option. However, PCI group in the meta-analysis mixed with bare-metal stents and DES but not comparing DES with CABG separately, which might lead to the results less robust [37]. The meta-analysis by Lee et al. [10] included 8 clinical studies and followed up 1 years. However, the number of patients in the CABG and DES groups was wrong in one study [38] and the total number of studies and patients was small, which may also lead to the results less robust. The meta-analysis by Zheng et al. [12] published in 2011 heavily based on observational studies (13 observational studies and 2 RCTs) and followed up to 5 years in two groups, however, abstracted and combined unadjusted risk estimates not only from
randomized trials but also from observational studies in the study, which was not robust in the conclusion.

Two recent meta-analyses including single RCT have been published. In one meta-analysis including 3 RCTs, Kajimoto et al. [9] showed that there was no significant difference in the risk of death and myocardial infarction MI in two groups but was superior to target vessel revascularization and major adverse cardiac and cerebrovascular events in CABG than in PCI groups at 1 year. So they believed that CABG remains the standard of care for the treatment of left main coronary artery disease. However, the meta-analysis included a large power article [39] with 1800 patients mixed with left main coronary artery disease and three-vessel coronary disease but not comparing the results of left main coronary artery disease in two groups separately, which also made the results not robust.

The meta-analysis by Desch et al. [40] including 4 RCTs showed that there were no significant differences in the clinical endpoints of death and myocardial infarction MI between the PCI and CABG groups. While stroke was more frequent in surgical patients, the risk of repeated revascularization was higher in PCI up to 2 years. So they believe PCI only as an alternative to CABG in anatomically suited patients and increased risk of adverse surgical outcomes. However, the meta-analysis included a article [41] that mixed with bare-metal stents and DES but not comparing DES with CABG separately, and the size of the study population was a bit small, which also made the results not robust.

In our study, however, we exclude the articles that mixed with left main coronary artery disease and three-vessel coronary disease but not comparing left main coronary artery disease in two groups separately or mixed with bare-metal stents and DES
but not comparing DES with CABG separately, and we included more studies (4 RCTs and 17 observational studies) and larger number of patients (total 8413), and we performed the systematic review using different method, which may be the reason of the different outcomes with the previous meta-analyses. We also performed the analysis of RCT and observational groups separately, there was no significant difference in death, myocardial infarction MI, cerebrovascular events or revascularization between RCT and observational groups. These also made our conclusion more robust.

**Quality of the evidence**

Some of the evidence GRADE level was low because most of the included studies were poor quality. Seventeen studies were observational studies and they were not performed the method of randomisation and allocation concealment, which might lead to selection bias and RR is exaggerated. Combined with not performing methods of blinding could result in performance, attrition and detection bias. These method limitations caused down grade of the quality of evidences. On the other hand, some differences in baseline characteristics among treatment groups might have an unknown influence on the estimated effects that would increase inconsistent results, and some trails in these groups had inconsistent results and high heterogeneity. All these caused down grade of the quality of evidences, too. What is more, only the articles in English were included in this analysis and we were unable to search for grey articles, which might be a source of potential publication bias in this study. Low quality of grade was not able to robust conclusion in some groups in this population.

However, some RRs of total or subtotal were large effect. All RCTs describe the method
of randomization and allocation concealment. These subgroups of RCT had consistent results and low heterogeneity, but the size of the study population of RCT was a bit small and the pooled analysis showed a wide CI. Therefore, some of the evidence GRADE level was moderate (Figure 10).

Other limitations should also be discussed in our study. To begin with, included studies only included four RCTs in our meta-analysis, and two RCTs had duplicate patients and most types of data of outcomes in the two studies were repeated. Therefore, in the future, more randomized studies to compare DES with CABG in patients with left main coronary artery disease are necessary. What is more, many studies’ period of follow-up was short and only three observational studies [23, 30, 31] reported long-term follow-up (5 years). Therefore, more longer-term results are necessary in the future.

**Conclusion**

Our meta-analysis indicates that DES has lower risk in the safety than CABG but superiority of CABG to DES for repeated revascularization in patients with ULMCAD in the 5 years after intervention. There was no difference in death, myocardial infarction MI, cerebrovascular events or revascularization between RCT and observational groups. Therefore, DES for ULMCAD may be a better alternative to CABG.

**abbreviations**

DES=drug-eluting stents; CABG=coronary artery bypass grafting; ULMCAD= unprotected
left main coronary artery disease

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**Competing interests**

The authors declare that they have no competing interests.

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**Author contributions**

QL contributed to the concept and design of the study, acquisition and interpretation of data, drafting of the article, and final approval of the version to be published. ZZ contributed to the acquisition, analysis, and interpretation of data; revision of the article; and final approval of the version to be published. RXY contributed to the concept and design of the study, analysis and interpretation of data, drafting and revision of the article, and final approval of the version to be published.
QL conceived the study, participated in the design, collected the data, performed statistical analyses, and drafted the manuscript. ZZ helped to collect the data and perform statistical analyses. RXY conceived the study, participated in the design, and helped to draft the manuscript. All authors read and approved the final manuscript.

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None

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**Competing interests**

The authors declare that they have no competing interests.
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17. Higgins JPT, Green S: *Cochrane Handbook for Systematic Reviews of*


coronary artery disease: 5-year results from the MAIN-COMPARE (Revascularization for Unprotected Left Main Coronary Artery Stenosis: Comparison of Percutaneous Coronary Angioplasty Versus Surgical Revascularization) registry. J Am Coll Cardiol 2010, 56:117-124.


revascularization. *J Am Coll Cardiol* 2008, **51**:538-545.
Figure Legend

Figure 1 Flow chart showing study selection process.

Figure 2 Comparison of the early outcomes (≤ 30 days or in-hospital early) between PCI and CABG groups.

Figure 3 Comparison of the outcome of death from 1 to 5 years between PCI and CABG groups.

Figure 4 Comparison of the outcome of composite endpoint of death, MI, cerebrovascular events from 1 to 5 years between PCI and CABG groups.

Figure 5 Comparison of the revascularization from 1 to 5 years between PCI and CABG groups.

Figure 6 Comparison of DES and CABG of MI in 1 year between RCT and observational groups.

Figure 7 Comparison of DES and CABG for the outcome of cerebrovascular events of 1 year between RCT and observational groups.

Figure 8 Comparison of DES and CABG for the outcome of death of 1 year between RCT and observational groups.

Figure 9 Comparison of DES and CABG for the outcome of revascularization of 1 year between RCT and observational groups.

Figure 10 Summary of finding for the main comparison.
<table>
<thead>
<tr>
<th>Study</th>
<th>Year</th>
<th>Patients (DES/CABG)</th>
<th>Study year</th>
<th>Study design</th>
<th>Age (years) (DES/CABG)</th>
<th>Outcome</th>
<th>Follow-up period</th>
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<td>Lee et al [27]</td>
<td>2006</td>
<td>50/123</td>
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<td>Park et al [31]</td>
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<td>death, TVR, MACCE</td>
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<td>Shimizu et al [34]</td>
<td>2010</td>
<td>64/89</td>
<td>2004–2007</td>
<td>observational</td>
<td>71/70</td>
<td>MI, TVR, stroke</td>
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</tbody>
</table>

MACCE, major adverse cardiac cerebrovascular events; MVD, multivessel disease; TVR, target vessel revascularization
### Table 2 Baseline Clinical Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>PCI</th>
<th>CABG</th>
<th>(P(X^2))</th>
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<tr>
<td>Number</td>
<td>3682</td>
<td>4731</td>
<td></td>
</tr>
<tr>
<td>Female/Sample size</td>
<td>756/2644</td>
<td>862/3725</td>
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<td>Hypertension/Sample size</td>
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<td>2529/4008</td>
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<td>893/2763</td>
<td>1306/3804</td>
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<td>1374/4009</td>
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<td>Previous MI/Sample size</td>
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<td>Previous stroke/Sample size</td>
<td>204/1882</td>
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<td>Previous PCI/Sample size</td>
<td>415/2022</td>
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<td>&lt;0.001</td>
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</table>

Comparison of preoperative variable in DES and CABG patients. All variables come from the individual studies included. RCA, right coronary artery; CRF, chronic renal failure