Systematic Review and Meta-Analysis

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Early versus late clinical outcomes following same day discharge after elective percutaneous coronary intervention

A systematic review and meta-analysis

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Abstract

Background: Nowadays 57% of the cardiologists based in the United Kingdom and 32% of the cardiologists based in Canada utilize same day discharge (SDD) following elective percutaneous coronary intervention (PCI) as a routine practice. In this analysis, we aimed to systematically assess early versus late clinical outcomes following SDD after elective PCI.

Methods: The Medical Literature Analysis and Retrieval System Online, the Cochrane Central, the Resources from the United States National Library of Medicine (www.ClinicalTrials.gov: http://www.clinicaltrials.gov) and EMBASE were carefully searched for relevant English publications which reported early versus late clinical outcomes in patients who were discharged on the same day following revascularization by PCI. Relevant clinical outcomes which were reported in the original studies were considered as the endpoints in this analysis. Odd ratios (OR) and 95% confidence intervals (CI) were used to represent the data, and RevMan 5.3 was used as the statistical software.

Results: A total number of 21, 687 participants (enrollment time period from the year 1998 to the year 2015) were assigned to this analysis. When early versus late clinical outcomes were compared in patients who were discharged on the same day following elective PCI, major adverse cardiac events (OR: 0.75, 95% CI: 0.31–1.79; $P = .51$), mortality (OR: 0.26, 95% CI: 0.06–1.06; $P = .06$), stroke (OR: 1.46, 95% CI: 0.72–2.94; $P = .29$), arrhythmia (OR: 1.30, 95% CI: 0.64–2.63; $P = .47$), hematoma (OR: 1.00, 95% CI: 0.60–1.66; $P = 1.00$) and major bleeding from access site (OR: 1.68, 95% CI: 0.22–12.85; $P = .62$) were not significantly different. Post-procedural myocardial infarction (OR: 2.01, 95% CI: 0.71–5.70; $P = .19$) and minor bleeding from access site (OR: 6.61, 95% CI: 0.86–50.66; $P = .07$) were also similarly manifested. However, re-hospitalization was significantly higher in those patients with late clinical outcomes (OR: 0.18, 95% CI: 0.07–0.44; $P = .0002$).

Conclusions: In those patients who were discharged from the hospital on the same day following elective PCI, no significant difference was observed in the assessed early versus late clinical outcomes. However, late clinical outcomes resulted in a significantly higher rate of re-hospitalization. Larger studies should confirm this hypothesis.

Abbreviations: MACEs = major adverse cardiac events, PCI = percutaneous coronary intervention, SDD = same day discharge.

Keywords: clinical outcomes, elective percutaneous coronary intervention, major adverse cardiac events, re-hospitalization, same day discharge

1. Introduction

Cardiovascular disease (CVD) is among the major causes of mortality in this new era.[1] Percutaneous coronary intervention (PCI) remains the most common option for majority of the patients (accounting for about 3.6% of all operating theatres in the United States[2]) and an approximate total number of 500, 000 procedures are carried out annually in the United States.[3] Following this invasive procedure, patients are observed for at least 24 hours before discharge from the hospital in order to prevent any post-procedural complication. However, with advanced development in Interventional cardiology including newer intra-procedural management guidelines, and considering the high daily hospital costs, and the total number of patients opting for this revascularization strategy requiring places to accommodate new patients, elective PCI on an outpatient basis for patients with stable coronary artery disease (CAD) has recently shown to be safe.[4] Same day discharge (SDD) following elective PCI was successfully being carried out in several PCI capable centers across the globe.[5–6]

Even if PCI practice has evolved resulting in a decline in the rate of post-procedural complications, hospitals and institutions might still not take the risk to implement SDD following this

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HL and WG contributed equally to this study and they are co-first authors.

Ethical approval was not applicable for this systematic review and meta-analysis.

All data and materials used in this research are freely available. References have been provided.

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invasive procedure in fear of unexpected unwanted complications as well as the unknown adverse events associated with this SDD instead of an overnight stay to watch for any complication.

SOCRATES (Study of Costs Realized After Percutaneous Coronary Intervention Employing Same Day Discharge) recently randomized patients for the study of SDD following elective PCI,[7] but unfortunately the study was terminated due to a lack of participants. However, a recent meta-analysis demonstrated similar clinical outcomes in patients who were discharged on the same day versus those patients who stayed overnight in the hospital post PCI.[8]

When considering SDD following PCI from the point of view of a physician, it was also necessary to consider it from the point of view of a patient. Many patients prefer recovering at home following this invasive procedure for various reasons including comfort, lower hospital cost, and other similar facilities.[4] Therefore, nowadays, 57% of the cardiologists based in the United Kingdom and 32% of the cardiologists based in Canada utilize SDD as a routine practice.[9] However, there is not enough evidence to support early and late clinical outcomes of SDD following coronary angioplasty.

In this analysis, we aimed to systematically assess early versus late clinical outcomes following SDD after elective PCI.

2. Methods

2.1. Search databases and search terms

MEDLARS (Medical Literature Analysis and Retrieval System Online), Cochrane Central, Resources from the United States National Library of Medicine (www.ClinicalTrials.gov: http://www.clinicaltrials.gov) and EMBASE were carefully searched with reference to the PRISMA study guideline,[10] for relevant English publications comparing early versus late clinical outcomes in patients who were discharged on the same day following revascularization by elective PCI.

The following search terms were used:

- "same day discharge and percutaneous coronary intervention";
- "same day discharge and PCI";
- "same day discharge and coronary angioplasty";
- "same day discharge and coronary intervention";
- "same day discharge and ambulatory";
- "same day discharge and PCI and clinical outcomes";
- "same day discharge and coronary artery intervention";
- "early discharge and percutaneous coronary intervention".

All the search databases were used to retrieve relevant publications using the above-mentioned search terms.

2.2. Inclusion and exclusion criteria

Studies were included if:

- They were randomized or observational cohorts/registries/retrospective studies comparing early versus late clinical outcomes in patients who were discharged on the same day following PCI;
- They consisted of patients with elective PCI.

Studies were excluded based on the following criteria:

- Either early or late clinical outcomes were not reported;
- They consisted of patients who were not discharged on the same day following PCI;
- They did not report similar outcomes for early and late follow-up time periods;
- They consisted of data which could not be used in this analysis;
- They were duplicated studies.

2.3. Types of participants, outcomes reported and follow-up time periods

All the participants were candidates for elective PCI who were discharged on the same day following this interventional procedure.

The clinical outcomes which were analyzed included:

- Major adverse cardiac events (MACEs) consisting of death, myocardial infarction, and repeated revascularization;
- Mortality;
- Post-procedural myocardial infarction (MI);
- Stroke;
- Arrhythmia;
- Major bleeding from access site;
- Minor bleeding from access site;
- Hematoma;
- Re-hospitalization.

Patients who were assigned to the early clinical outcome group had a mean follow-up time period ranging from hours after the procedure to 7 days post-procedure (with the exception of 1 study which had an early follow-up of 30 days).

Patients who were assigned to the late clinical outcome group had a mean follow-up time period ranging from over 24 hours to 30 days (with the exception of 1 study which had a late follow-up time period of 1 year).

The types of participants, outcomes which were assessed and the respective follow-up time periods have been reported in Table 1.

2.4. Data extraction and quality assessment

The total number of participants who were discharged on the same day following PCI, the total number of events, the respective clinical outcomes, the time period of patients' enrollment, and data referring to the baseline features of the participants were carefully extracted and checked by 4 independent reviewers. Any disagreement which followed was resolved by consensus.

The methodological quality of the trials was assessed with respect to the criteria suggested by the Cochrane Collaboration.[11]

2.5. Statistical analysis

The latest version of the RevMan software (version 5.3) was used to carry out the statistical analysis. Odds ratios (OR) and 95% confidence intervals (CI) were generated to represent the data following the subgroup analysis.

Heterogeneity was assessed by the Q statistic and the I^2 statistic tests respectively. During the subgroup analysis, a P value less or equal to .05 was considered statistically significant. When the I^2 value was used to assess heterogeneity, an increasing value of I^2 indicated an increased level of heterogeneity.

A fixed effects ($I^2 < 50\%$) statistical model or a random effects ($I^2 > 50\%$) statistical model was used based on the I^2 value which was obtained.

Sensitivity analysis was carried out using an exclusion method, and publication bias were assessed using funnel plots.

2.6. Ethical approval

Ethical or board review approval was not required for this type of study.

Table 1

Types of participants, outcomes reported, discharge period, follow-up time periods.

Studies	Discharge period following PCI	Types of participants	Outcomes reported	Follow-up time period
Agarwal 2017[12]	SDD	Outpatient elective PCI	All repeat admissions, procedural/device complications, non-specific chest pain, stroke/TIA, arrhythmia, AMI	7 days versus 30 days
Aydin 2014[13]	SDD	Elective PCI	Minor bleeding, major bleeding, post-procedural MI, death, atrial fibrillation, stroke	< 24 hours versus > 24 hours
Clavijo 2016[14]	SDD	Stable and low risk ACS + PCI	MACEs, major bleeding, recurrent admission	30 days versus 1 year
Cordoba 2017[15]	SDD	Outpatient elective PCI	MACEs, death, AMI, stroke, bleeding requiring the need for transfusion, re-admission, hematoma	24 hours versus 30 days
Heyde 2007[16]	SDD	Elective PCI	MACEs, death, MI, stroke, re-admission, hematoma	< 24 hours versus 30 days
Jabara 2008[17]	SDD	Elective PCI	Minor bleeding, major bleeding, post-procedural MI, arrhythmia, Death, stroke	6 hours versus > 24 hours
Kim 2013[18]	SDD	Elective PCI	MI, bleeding, re-admission	7 days versus 30 days
Muthusamy 2013[19]	SDD	Elective PCI	MACE, major bleeding, minor bleeding, re-admission	24 hours versus 7 days
Rao 2011[20]	SDD	Elective PCI	Death, re-admission	2 days versus 30 days
Slagboom 2005[21]	SDD	Outpatient elective PCI	Death, MI	24 hours versus 30 days
Ziakas 2003[22]	SDD	Elective PCI	Bleeding, hematoma	24 hours versus 30 days

ACS = acute coronary syndrome, AMI = acute myocardial infarction, MACEs = major adverse cardiac events, MI = myocardial infarction, PCI = percutaneous coronary intervention, SDD = same day discharge, TIA = transient ischemic attack.

3. Results

3.1. Search outcomes

A total number of 396 publications were obtained through search databases. The 4 reviewers carefully assessed the titles and abstract and publications which were irrelevant were directly eliminated (345 articles).

Fifty-one (51) full-text articles were assessed for eligibility.

Another careful assessment of the full-text articles was carried out and further irrelevant articles were eliminated: meta-analysis

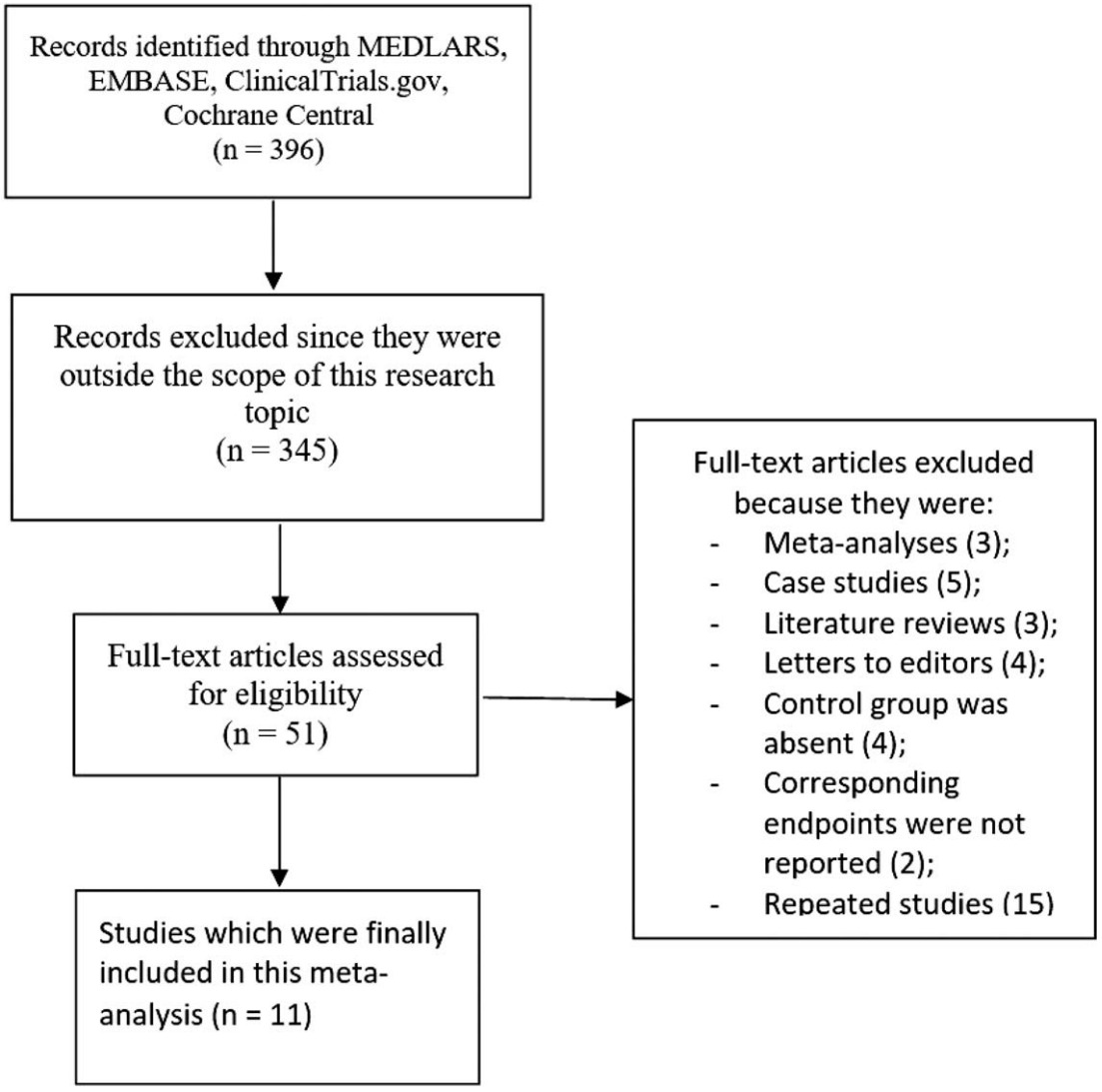

Figure 1. Flow diagram representing the study selection.

Table 2

Main features of the studies.

Studies	Type of study	Total no of patients with SDD (n)	Time period of patients' enrollment	Antiplatelet medications upon discharge	Radial or femoral access
Agarwal 2017	OS	17089	2009–2013	NR	NR
Aydin 2014	OS	155	NR	ASA + clopidogrel	Transradial
Clavijo 2016	RCT	50	2011–2014	NR	NR
Cordoba 2017	OS	533	2013–2015	NR	Transradial and transulnar
Heyde 2007	OS	403	2000–2003	NR	NR
Jabara 2008	OS	450	2004–2007	NR	Transradial
Kim 2013	RCT	150	2008–2010	NR	Transfemoral
Muthusamy 2013	OS	200	2008–2011	ASA + clopidogrel or prasugrel	NR
Rao 2011	OS	1339	2004–2008	NR	NR
Slagboom 2005	RCT	375	NR	ASA	Transradial and transulnar
Ziakas 2003	OS	943	1998–2001	NR	Transradial
Total no of patients (n)		21, 687			

ASA = aspirin, NR = not reported, OS = observational study, RCT = randomized controlled trials, SDD = same day discharge.

(3), case studies (5), literature reviews (3), letters to editors (4), control group was absent (8), corresponding endpoints were not reported (2), repeated studies (15).

Finally, 11 articles[12–22] were selected to be included in this analysis as shown in Figure 1.

3.2. Main features of the studies

The main features of the studies have been listed in Table 2.

A total number of 21, 687 participants (enrollment time period from the year 1998 to the year 2015) were assigned to this analysis. Three studies were randomized trials whereas the remaining 8 studies were observational cohorts. Most of the patients underwent re-vascularization by the transradial approach and aspirin + clopidogrel were the main anti-platelet agents which were continually being used after the procedure.

3.3. Baseline characteristics of the participants

The baseline characteristics of the participants have been listed in Table 3.

The participants were mainly male patients (74.0–88.0) % with a mean age of (56.5–73.0) years as shown in Table 3. Other features including the several cardiovascular risk factors (hypertension, diabetes mellitus, dyslipidemia, and current smoking) have also been listed in the Table. Overall, there was no significant difference in baseline features reported between the participants who were assigned to the early versus the late follow-up groups.

3.4. Main results of this analysis

When early versus late clinical outcomes were compared in patients who were discharged on the same day following PCI, MACEs (OR: 0.75, 95% CI: 0.31–1.79; $P = .51$), mortality (OR: 0.26, 95% CI: 0.06–1.06; $P = .06$), stroke (OR: 1.46, 95% CI: 0.72–2.94; $P = .29$), arrhythmia (OR: 1.30, 95% CI: 0.64–2.63; $P = .47$), hematoma (OR: 1.00, 95% CI: 0.60–1.66; $P = 1.00$) and major bleeding from access site (OR: 1.68, 95% CI: 0.22–12.85; $P = .62$) were not significantly different as shown in Figure 2.

Post-procedural MI (OR: 2.01, 95% CI: 0.71–5.70; $P = .19$) and minor bleeding from access site (OR: 6.61, 95% CI: 0.86–50.66; $P = .07$) were also similarly manifested as shown in Figure 3. However, re-hospitalization was significantly higher in those patients with late clinical outcomes (OR: 0.18, 95% CI: 0.07–0.44; $P = .0002$) as shown in Figure 3.

The main results of this analysis have been summarized in Table 4.

Table 3

Baseline features of the studies.

	Mean age (years)	Males (%)	HBP (%)	DM (%)	DSL (%)	CS (%)
Studies	E/L	E/L	E/L	E/L	E/L	E/L
Agarwal 2017	64.7/64.7	74.0/74.0	73.9/73.9	37.8/37.8	–	–
Aydin 2014	62.0/62.0	76.8/76.8	68.1/68.1	31.1/31.1	54.7/54.7	52.8/52.8
Clavijo 2016	58.5/58.5	88.0/88.0	84.0/84.0	40.0/40.0	68.0/68.0	12.0/12.0
Cordoba 2017	66.3/66.3	76.2/76.2	74.6/74.6	37.9/37.9	70.7/70.7	19.1/19.1
Heyde 2007	62.1/62.1	81.0/81.0	41.0/41.0	16.0/16.0	65.0/65.0	25.0/25.0
Jabara 2008	59.0/59.0	87.0/87.0	64.0/64.0	27.0/27.0	71.0/71.0	30.0/30.0
Kim 2013	56.5/56.5	74.5/74.5	–	46.2/46.2	48.8/48.8	13.3/13.3
Muthusamy 2013	63.2/63.2	75.0/75.0	89.5/89.5	27.5/27.5	77.0/77.0	63.0/63.0
Rao 2011	73.0/73.0	74.5/74.5	80.3/80.3	33.1/33.1	78.5/78.5	–
Slagboom 2005	60.0/60.0	77.5/77.5	36.5/36.5	14.5/14.5	50.5/50.5	50.0/50.0
Ziakas 2003	63.5/63.5	79.7/79.7	37.9/37.9	18.8/18.8	42.5/42.5	37.7/37.7

E = early clinical outcome group, L = late clinical outcome group, HBP = high blood pressure, DM = diabetes mellitus, DSL = dyslipidemia, CS = current smoker.

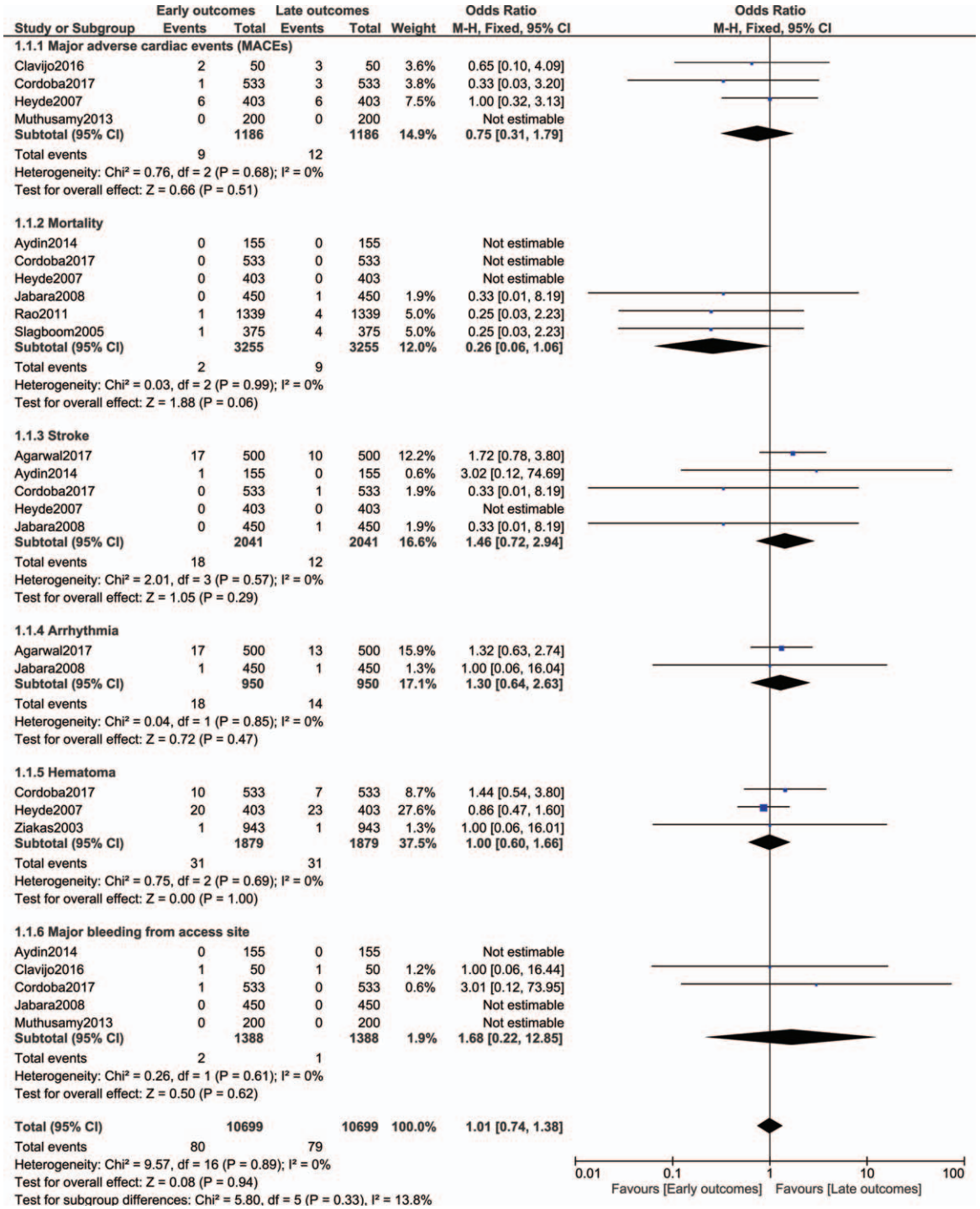

Figure 2. Early versus late clinical outcomes observed in patients who were discharged on the same day following coronary angioplasty (Part 1).

3.5. Sensitivity analysis and publication bias

Consistent results were obtained throughout. Even when the study with the largest number of patients was excluded, no significant difference in results was observed. Post-procedural MI (OR: 2.45, 95% CI: 0.47–12.72; $P = .29$), and re-hospitalization (OR: 0.16, 95% CI: 0.04–0.59; $P = .006$) did not significantly differ as compared to the main results.

By assessing the funnel plots which were generated from the RevMan software, only low evidence of publication bias was observed among all the studies that assessed the events reported in early versus late clinical outcomes following SDD after PCI as shown in Figures 4 and 5.

4. Discussion

Our analysis comparing early versus late clinical outcomes in patients who were discharged on the same day following PCI showed no significant difference between the 2 groups based on the outcomes that were assessed. However, re-hospitalization

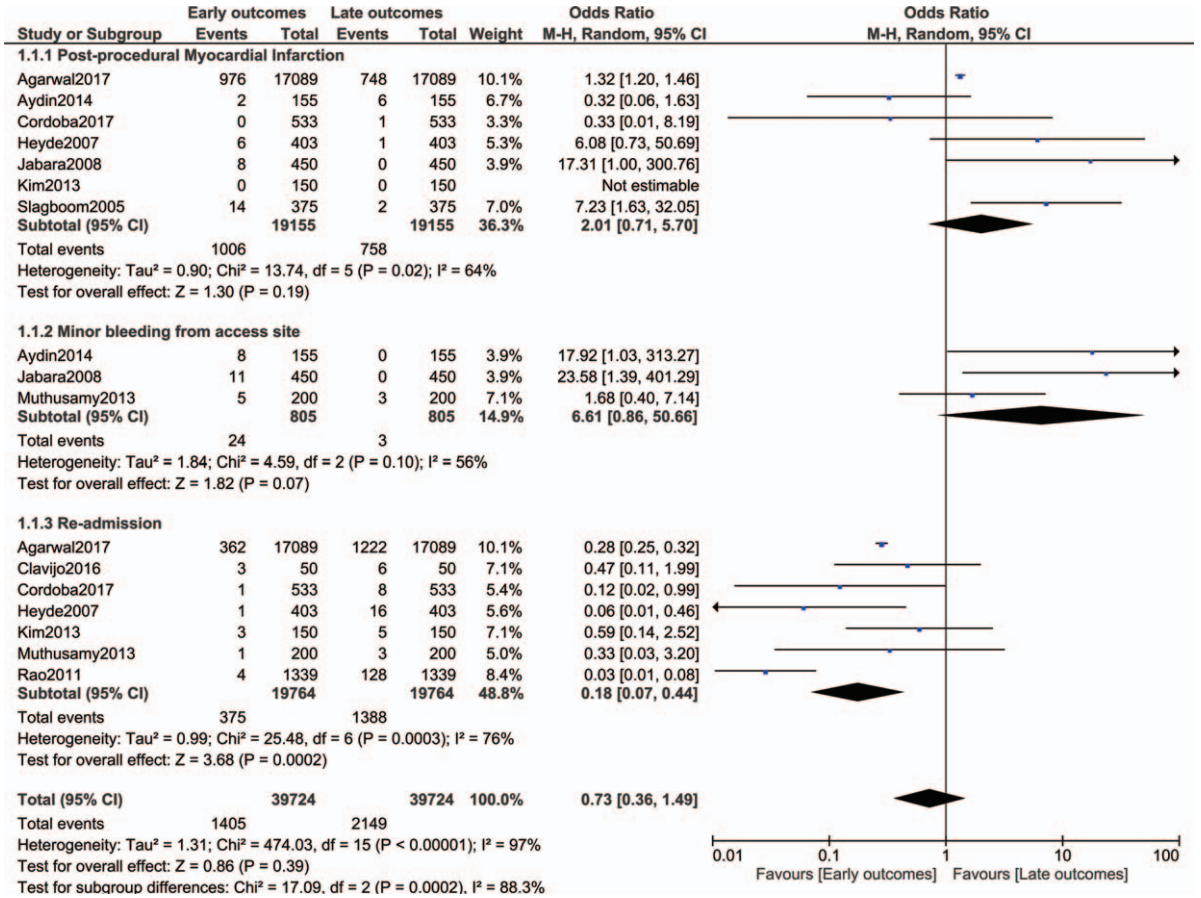

Figure 3. Early versus late clinical outcomes observed in patients who were discharged on the same day following coronary angioplasty (Part 2).

was significantly higher in those patients with late clinical outcomes after PCI.

A meta-analysis which compared SDD versus overnight stay in the hospital following PCI showed the former not to be associated with major complications, and the authors stated that SDD appeared safe in selected patients undergoing elective PCI.[23] Moreover, even if the femoral access was more delicate in comparison to the radial or ulnar access for intervention, a retrospective study which was carried out with participants assigned to elective PCI at the Mount Sinai Hospital in New York, showed that if the respective protocol was correctly followed, SDD was completely safe in uncomplicated elective PCI via the femoral access.[24]

Eleven hundred ninety elective PCI were retrospectively reviewed at the Red Cross General Hospital to assess for the feasibility and safety of SDD for selected patients undergoing complex PCI using the forearm approach. The authors concluded that SDD was safe in selected patients without any complication.[25]

In a recent study which evaluated time trend in SDD to compare certain clinical outcomes including mortality, bleeding and acute kidney injury following contrast injection during the

Table 4

Results of this analysis.

Outcomes assessed	Total no of studies involved (n)	OR with 95% CI	*P* value	I^2 value (%)
MACEs	4	0.75 [0.31–1.79]	0.51	0
Mortality	6	0.26 [0.06–1.06]	0.06	0
Stroke	5	1.46 [0.72–2.94]	0.29	0
Arrhythmia	2	1.30 [0.64–2.63]	0.47	0
Hematoma	3	1.00 [0.60–1.66]	1.00	0
Major bleeding from access site	5	1.68 [0.22–12.85]	0.62	0
Minor bleeding from access site	3	6.61 [0.86–50.66]	0.07	56
Post-procedural MI	7	2.01 [0.71–5.70]	0.19	64
Re-admission	7	0.18 [0.07–0.44]	0.0002	76

CI = confidence intervals, MACEs = major adverse cardiac events, MI = myocardial infarction, OR = odds ratios.

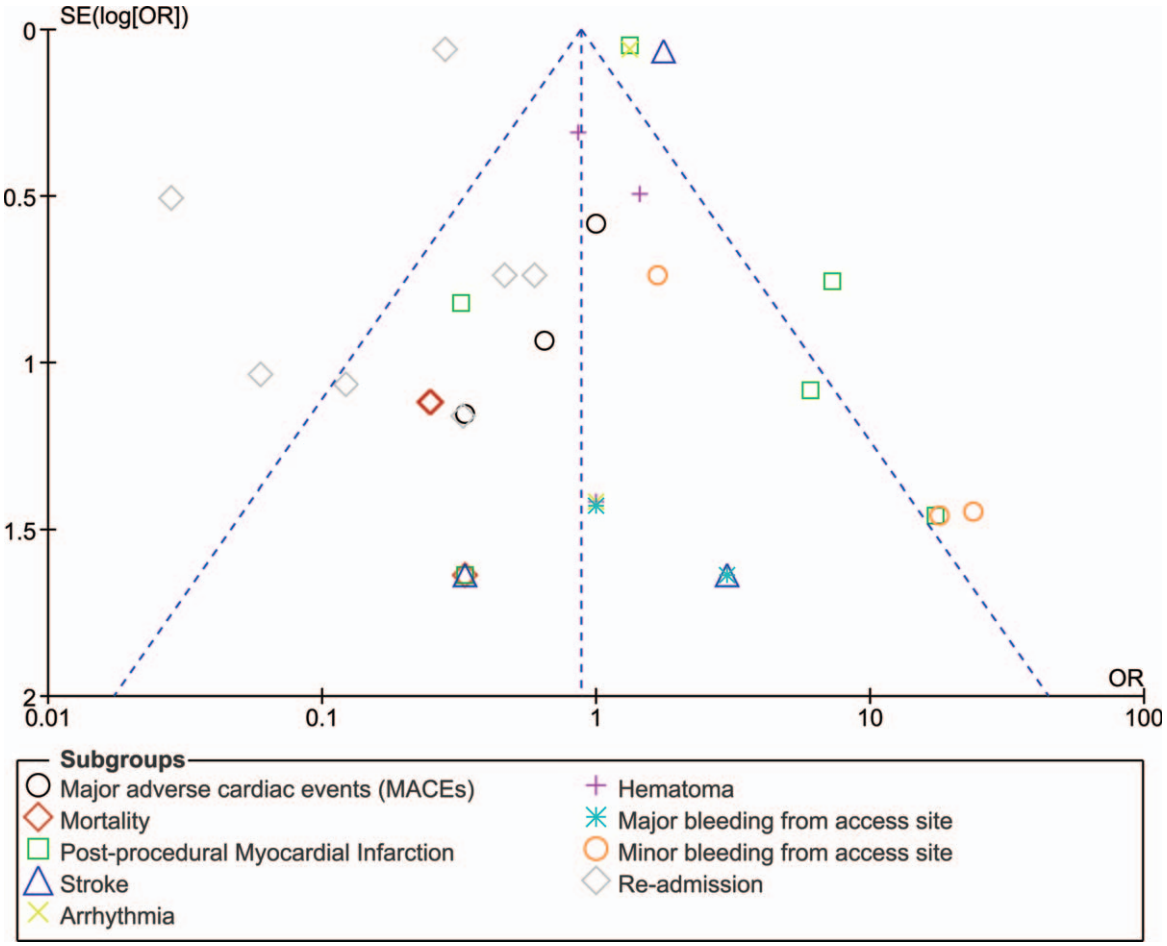

Figure 4. Funnel plot showing publication bias (A).

procedure, and which evaluated patients' satisfaction and patients' hospital costs for SDD versus overnight stay following the invasive procedure, the authors concluded that with a patient-centered approach, SDD increased tremendously with a safety success rate of over 75% of all the patients who underwent elective PCI.[4] The authors also stated that the patients were very satisfied with the lower hospital cost following this SDD following coronary angioplasty. This strategy should be beneficial to health cost in the future.[5]

Now that we know SDD was safe in selected patients following elective PCI, our analysis showed no significant difference with respect to the early versus late clinical outcome. However, re-hospitalization was significantly due to late clinical outcomes and further workups should be carried out on this particular aspect.

5. Limitations

Limitations were as follow: first of all, the early and late time period varied from study to study. Not all the study reported post-interventional outcomes during the same follow-up time period. Therefore, even if this is not a major problem, it might be considered as a minor limitation of this analysis. However, in order to resolve this limitation, 4 studies with the same early and late follow-up time periods were also compared and a result similar to the main analysis was obtained. MACEs (OR: 0.78, 95% CI: 0.29–2.09; $P=.62$), re-hospitalization (OR: 0.08, 95% CI: 0.02–0.34; $P=.0007$) and results for the other outcomes were not significantly different with reference to the results of the main analysis. Secondly, due to the inclusion of several observational studies might have introduced bias and could be another limitation of this analysis. In addition, another limitation might be the fact that adverse clinical outcomes could have also been due to anti-platelet agent non-compliance which was not reported in the original study. Even anti-platelet agents which were used by the participant's post PCI were not stated in some of the original studies. This might have had an influence on the main results. At last, even if the total number of participants was enough to reach a robust conclusion, an even larger number of participants might have been more advantageous.

6. Conclusions

In those patients who were discharged from the hospital on the same day following elective PCI, no significant difference was observed in the assessed early versus late clinical outcomes. However, late clinical outcomes resulted in a significantly higher rate of re-hospitalization. Larger studies should confirm this hypothesis.

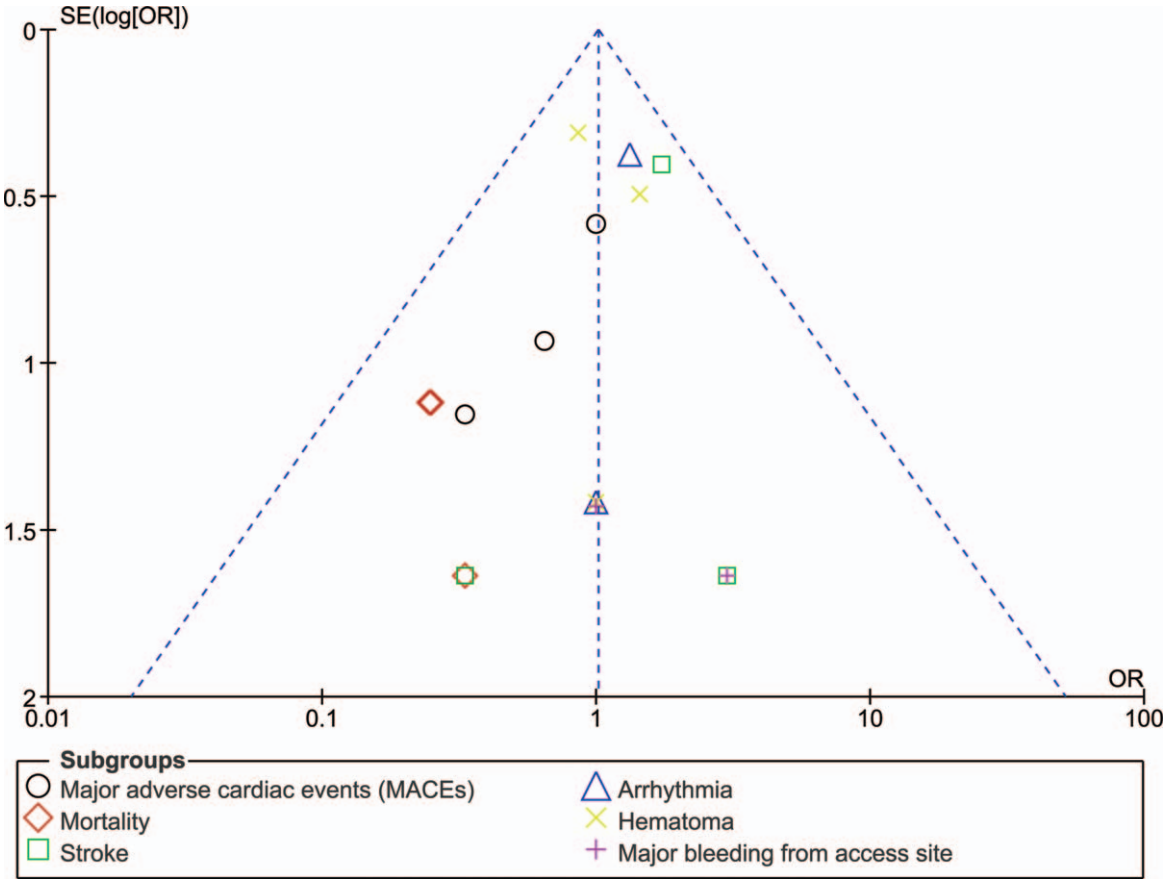

Figure 5. Funnel plot showing publication bias (B).

Author contributions

HL, WG, YZ, and BH were responsible for the conception and design, acquisition of data, analysis and interpretation of data, drafting the initial manuscript and revising it critically for important intellectual content. HL and WG contributed equally as first co-authors and wrote the final draft. All the authors approved the manuscript as it is.

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Writing – original draft: Hongtao Lu, Wenjun Guan, Hong Bao.
Writing – review & editing: Hongtao Lu, Wenjun Guan, Hong Bao.

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