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Original Article

Clinical and angiographic outcomes of rotational atherectomy for patients with calcified coronary lesions: a meta-analysis of randomized and observational studies

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Abstract: Rotational atherectomy (RA) before stenting is still controversial. We aim to evaluate the long-term clinical and angiographic outcomes of RA for patients with calcified coronary lesions after stent implantation. A systematic literature search of Medline, Embase, Cochrane and Ovid Databases were conducted. The clinical endpoints comprised major adverse cardiovascular events (MACEs), target lesion revascularization (TLR), and myocardial infarction (MI). The angiographic outcomes include acute gain, late lumen loss, and restenosis rate. Five randomized controlled trials (RCTs) and thirteen observational studies comprising 5,340 patients were included. Pooled analysis indicated that RA followed by stent decreased the rate of TLR (odds ratio (OR), 0.69; 95% confidence interval (CI), 0.48-0.99; *P* = 0.04), restenosis (OR, 0.54; 95% CI, 0.40-0.75; *P* = 0.0002), and have a better acute gain (weighted mean difference (WMD), 0.28; 95% CI, 0.18-0.37; *P*<0.00001). However, the risk of MI was significantly higher in the RA followed by stent group than the stent-only group (OR, 1.63; 95% CI, 1.15-2.31; P = 0.006). There were no significant differences in the incidence of MACEs (OR, 0.78; 95% CI, 0.46 to 1.32; P = 0.36) and late lumen loss (WMD, -0.03; 95% CI, -0.14 to 0.09; P = 0.65) between the two groups. This meta-analysis confirmed that RA followed by stent is superior to stent alone in terms of TLR, better acute gain, and restenosis during long-term periods. But a higher MI risk existed in patients treated by RA followed by stent technique.

Keywords: Rotational atherectomy, calcified coronary lesions, stents

Introduction

Rotational atherectomy (RA) was introduced in 1988 as a dedicated tool to facilitate the delivery and the deployment of stents in the severely calcified coronary lesions by plaque debulking and smoothing of the inner vascular lumen [1]. Thus, RA increases the compliance of resistant lesions, allowing balloon dilation and stent deployment to be accomplished successfully. Several studies have suggested that the use of RA followed by stent implantation to treat severely calcified lesions may achieve higher procedural success [2-10, 12-18]. However, other studies in this regard failed to find the effect of RA on stent implantation outcome [11, 19]. Furthermore, data on the efficacy and safety of RA in calcified lesions is derived from case reports and single-center experiences and there is no conclusive evidence supporting the use of RA in selected lesions prior to stent implantation improving long-term outcomes.

To evaluate the clinical and angiographic outcomes after RA followed by stent implantation in patients with coronary artery disease, we performed an updated meta-analysis to determine whether patients with severely calcified lesions will benefit from a strategy combining the RA technique and evaluate the long term clinical outcomes.

Methods

Search strategy and selection criteria

The published research was scanned by formal searches of electronic databases (PubMed, EMBASE, Web of Science and the Cochrane

Table 1. Main characteristics of the studies included in the Meta-analysis

First author, Year (Ref. #)	Design, study name	Patients sample size (N)	Lesions sample size (N)	Angiographic follow-up (Months)	Maximal length of clinical follow-up (Months)	Target lesion
Moussa I, et al 1998 [2]	Prospective registry study, SOLD	75/75	75/75	6	18	Ostial and bifurcation lesions
Kobayashi Y, et al 1998 [3]	Retrospective case-control study	37/163	37/163	6	6	LAD
Bramucci E, et al 1998 [4]	Prospective case-control study	100/94	94/94	6	14	Proximal non-tortuous artery
Muramatsu T, et al 2000 [5]	Retrospective case-control study	27/47	27/47	5.8	5.8	Ostial lesions
Ahmed JM, et al 2000 [6]	Retrospective case-control study	133/187	139/201	12	12	Ostial vein graft
Karvouni E, et al 2001 [7]	Retrospective case-control study	31/31	62/62	6	12.3	Bifurcation
Park SJ, et al 2001 [8]	Retrospective case-control study	40/87	40/87	6	25.5	Unprotected left main
Aizawa T, et al 2001 [9]	RCT, DESIRE	251/250	251/250	6	6	Broad inclusion subset
Airoldi F, et al 2003 [10]	Retrospective case-control study	46/71	46/71	5.9	7.9	Ostial LAD
Stankovic G, et al 2004 [11]	RCT, AMIGO	381/372	381/372	8	12	Broad inclusion subset
Kawamura A, et al 2004 [12]	Retrospective case-control study	64/69	64/69	6.1	6.1	Broad inclusion subset
Kim YH, et al 2004 [13]	RCT	44/42	44/42	6	18.6	Ostial LAD
Chung CM, et al 2004 [14]	Retrospective case-control study	44/42	44/42	6	6	Ostial lesions
Clavijo LC, et al 2006 [15]	Retrospective case-control study	81/69	81/69	NA	6	Broad inclusion subset
Tsuchikane E, et al 2008 [16]	RCT, DOCTORS	138/128	138/128	6	12	CTO
Tamekiyo H, et al 2009 [17]	Retrospective case-control study	223/1604	162/1477	7	24	Broad inclusion subset
Fujimoto H, et al 2010 [18]	Retrospective case-control study	26/28	26/28	7.9	12	Broad inclusion subset
Abdel-Wahab M, et al 2013 [19]	RCT, ROTAXUS	120/120	123/132	9	9	Broad inclusion subset

RCT, randomized controlled trials; LAD, left anterior descending coronary artery; CTO, chronic total coronary occlusions.

Central Register of Controlled Trials) up to February 2015. MeSH terms and key words included in the search were related to "coronary atherectomy", "atherectomy", "debulking", "stent", as well as a combination of the terms "calcified coronary lesions", and "coronary artery disease". The inclusion criteria were as follows: 1) the studies included a direct comparison of RA before stenting versus stenting alone; 2) patients with calcified coronary lesions; 3) reporting clinical outcomes; and 4) the follow-up time was at least 3 months. Exclusion criteria were defined as: 1) duplicate publications; 2) ongoing studies; 3) no control studies; and 4) studies lack of baseline or follow-up data.

Data extraction

Two independent investigators reviewed each report to determine its eligibility and then extracted and tabulated all of the relevant data. Disagreement was resolved by consensus between the two authors. The following information was obtained from each article: first author, year of publication, study design, patients and calcified coronary lesions sample size, clinical and angiographic follow-up period, clinical and angiographic events from included trials.

Endpoints

The primary clinical endpoint is composite major adverse cardiovascular events (MACEs). The secondary clinical endpoints included target lesion revascularization (TLR), and myocardial infarction (MI). Angiographic outcomes involving acute gain, late lumen loss, and restenosis. Individual protocol definitions were used to define the clinical endpoints.

Statistical analysis

All analyses were performed using Review Manager 5.0 software (available from The

Table 2. Angiographic data from single studies

First author, Year (Ref. #)	Acute gain (mm)		Late loss (mm)		Restenosis rate (%)	
	RA+stent	Stent alone	RA+stent	Stent alone	RA+stent	Stent alone
Moussa I, et al 1998 [2]	2.63±0.61	2.30±0.51	0.91±0.94	1.02±0.75	11	21
Kobayashi Y, et al 1998 [3]	2.84±0.52	2.27±0.46	NA	NA	6.3	23.1
Bramucci E, et al 1998 [4]	2.43±0.55	2.20±0.56	0.82±0.67	1.04±0.71	6.8	30.5
Muramatsu T, et al 2000 [5]	2.20±0.65	1.60±0.65	1.20±1.11	1.20±0.90	20	43
Ahmed JM, et al 2000 [6]	2.42±0.68	2.02±0.68	NA	NA	NA	NA
Karvouni E, et al 2001 [7]	2.32±0.72	1.97±0.70	1.03±0.79	1.19±0.85	28.8	43.5
Park SJ, et al 2001 [8]	3.10±0.55	2.90±0.55	NA	NA	8	23
Aizawa T, et al 2001 [9]	2.10±0.40	1.87±0.41	NA	NA	15	16
Airoldi F, et al 2003 [10]	2.40±0.78	2.13±0.80	0.80±0.63	1.05±0.84	13.8	33.3
Stankovic G, et al 2004 [11]	1.77±0.61	1.74±0.56	0.79±0.76	0.69±0.66	26.7	22.1
Kawamura A, et al 2004 [12]	2.61±0.78	2.15±0.87	0.93±0.93	0.70±0.83	12.5	18.8
Kim YH, et al 2004 [13]	2.80±0.52	5±0.7	1.70±0.91	50±0.70	28	37
Chung CM, et al 2004 [14]	2.57±0.59	2.56±0.58	0.91±0.85	1.26±0.78	17	22
Clavijo LC, et al 2006 [15]	NA	NA	NA	NA	NA	NA
Tsuchikane E, et al 2008 [16]	NA	NA	NA	NA	23.8	34.6
Tamekiyo H, et al 2009 [17]	NA	NA	NA	NA	NA	NA
Fujimoto H, et al 2010 [18]	NA	NA	0.61±0.98	1.05±1.02	17.4	42.3
Abdel-Wahab M, et al 2013 [19]	1.56±0.43	1.44±0.49	0.44±0.58	0.31±0.52	11.4	10.6

RA, rotational atherectomy; NA, not available.

Table 3. Clinical events data of the studies included in the Meta-analysis

First author, Year (Ref. #)	TLR (n) (RA+stent/ Stent)	MACEs (n) (RA+stent/ Stent)	MI (n) (RA+stent/ Stent)
Moussa I, et al 1998 [2]	5/14	NA/NA	NA/NA
Kobayashi Y, et al 1998 [3]	5/9	NA/NA	NA/NA
Bramucci E, et al 1998 [4]	3/15	4/19	0/3
Muramatsu T, et al 2000 [5]	0/5	NA/NA	NA/NA
Ahmed JM, et al 2000 [6]	26/34	3/4	2/1
Karvouni E, et al 2001 [7]	9/14	9/15	0/0
Park SJ, et al 2001 [8]	2/13	1/0	0/0
Aizawa T, et al 2001 [9]	24/40	NA/NA	NA/NA
Airoldi F, et al 2003 [10]	4/15	4/17	3/5
Stankovic G, et al 2004 [11]	75/70	21/16	16/13
Kawamura A, et al 2004 [12]	7/9	NA/NA	7/1
Kim YH, et al 2004 [13]	5/5	3/2	0/0
Chung CM, et al 2004 [14]	16/21	NA/NA	NA
Clavijo LC, et al 2006 [15]	3/3	8/9	1/1
Tsuchikane E, et al 2008 [16]	37/50	34/43	4/1
Tamekiyo H, et al 2009 [17]	67/276	78/327	21/66
Fujimoto H, et al 2010 [18]	3/10	NA/NA	0/2
Abdel-Wahab M, et al 2013 [19]	14/15	29/34	8/7

TLR, target lesion revascularization; MACEs, major adverse cardiovascular events; MI, myocardial infarction; NA, not available.

Cochrane Collaboration at http//www.cochrane.org). Pooled odds ratios (ORs) or weighted mean differences (WMD) with 95% confidence intervals (CI) were calculated using the Mantel-Haenszel method for fixed effects and the DerSimonian-Laird method for random effects. We tested heterogeneity of the included studies with Q statistics and extent of inconsistency between results with I^2 statistics [20]. Possibility of publication bias was assessed by funnel plot analysis. Sensitivity analysis was also done by omitting one study at a time to examine influence of one study on the overall summary estimate. Data are presented as ORs or WMD with 95% confidence intervals (CIs), $P<0.05$ were considered statistically significant. This study was performed in compliance with the Preferred Reporting Items for

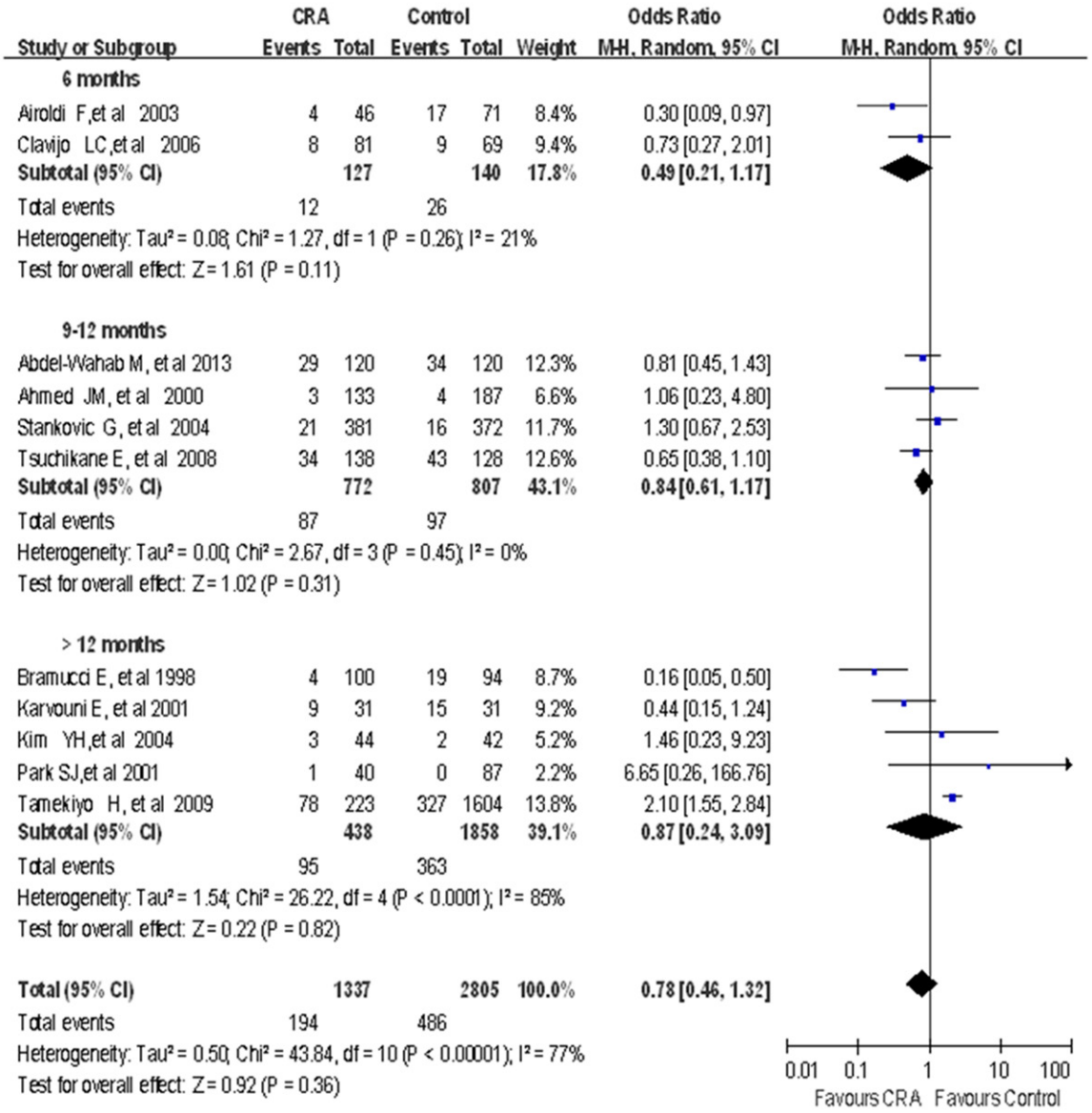

Figure 1. Comparison of rotational atherectomy combined with stent versus stent-only for the clinical outcome of major adverse cardiovascular events (MACEs).

Systematic reviews and Meta-Analyses (PRISMA) statement [21].

Results

Description of studies

The initial search generated 1386 reports, of which 1368 were excluded because of inconsistencies with selection criteria. Ultimately, 18 published studies were included [2-19]. A total of 1,861 patients undergoing RA before stent and 3,479 patients undergoing stent alone were included in the final meta-analysis. Five studies were randomized controlled trials (RCTs) [9, 11, 13, 16, 19], and 13 were non-randomized controlled trials (non-RCTs) [2-8, 10, 12, 14, 15, 17, 18]. Length of clinical follow-up varied between 5.8 months and 25.5 months, and length of angiographic follow-up between 5.8 months and 12 months after the index procedure. The clinical characteristics of patients included in the meta-analysis are reported in **Tables 1-3**. All studies were published in English.

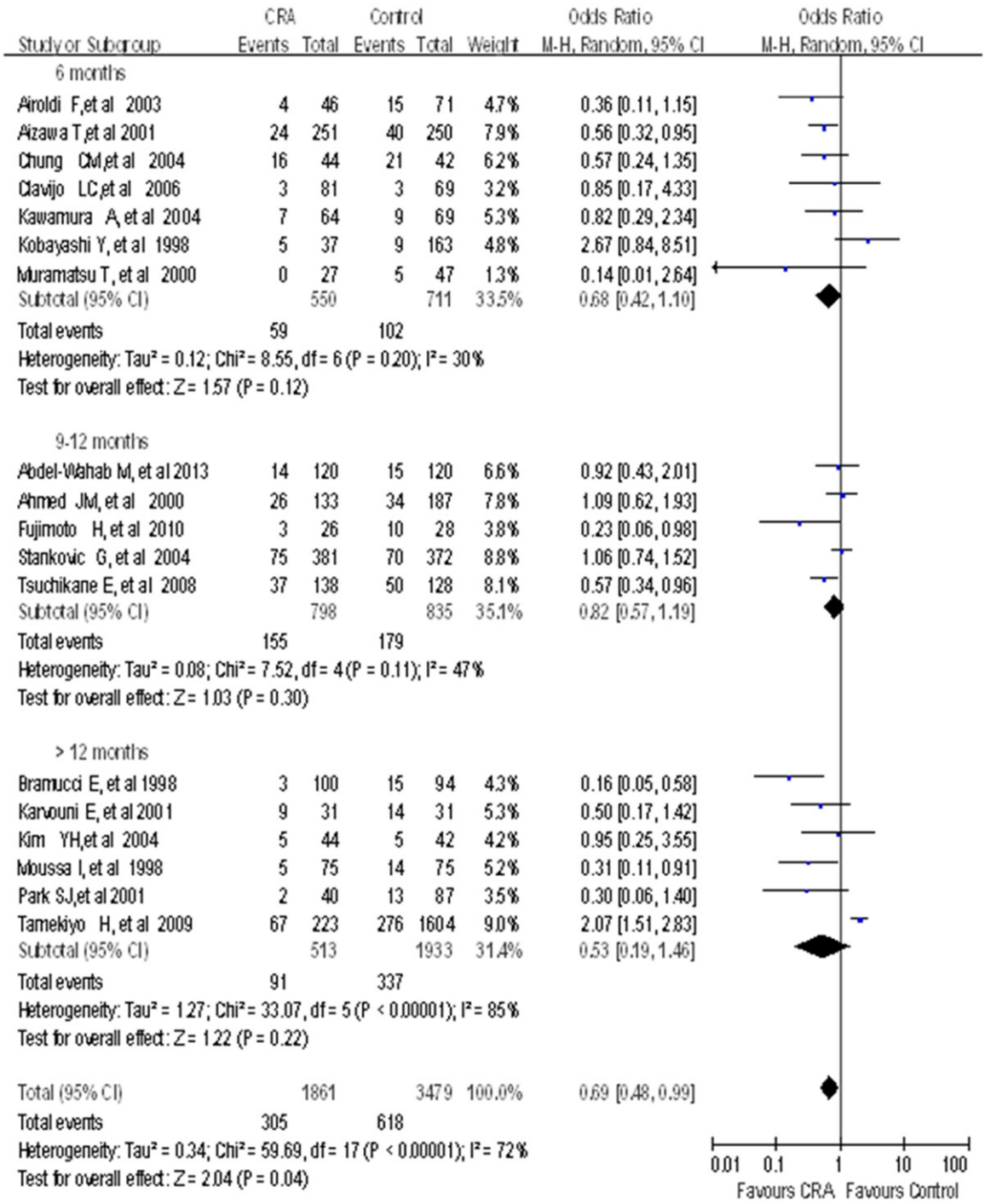

Figure 2. Comparison of rotational atherectomy combined with stent versus stent-only for the clinical outcome of target lesion revascularization (TLR).

Data synthesis

Clinical endpoints

MACEs: Data for MACEs were available from 11 studies [4, 6-8, 10, 11, 13, 15-17, 19] including 4,142 patients in whom 680 events were recorded. Pooled effects showed no significant difference in the incidence of MACEs between the RA followed by stent and stent-only groups (OR, 0.78; 95% CI, 0.46-1.32; P = 0.36). Statistical heterogeneity was evident among

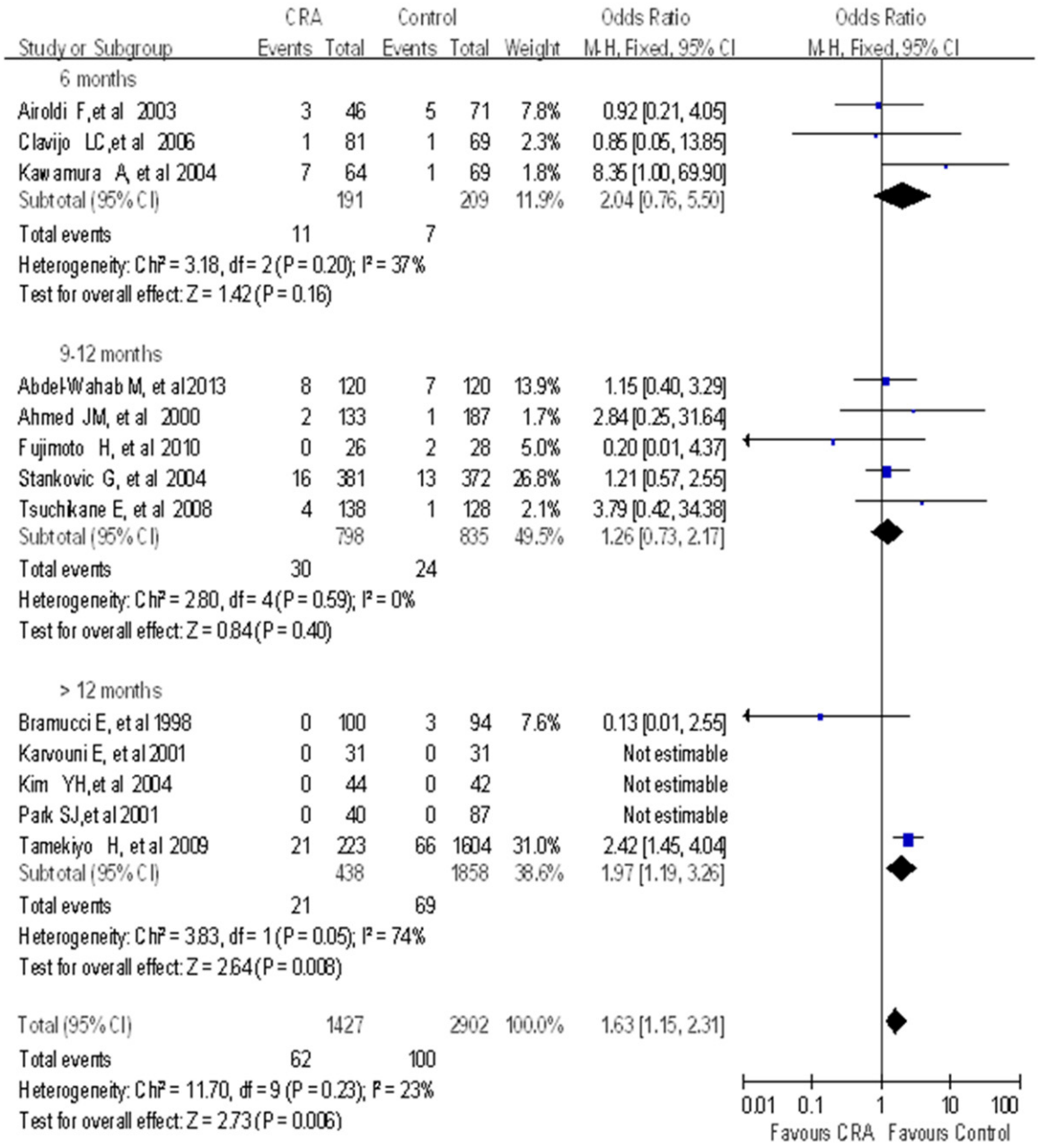

Figure 3. Comparison of rotational atherectomy combined with stent versus stent-only for the clinical outcome of myocardial infarction (MI).

these studies (P<0.00001, I^2 = 77%) (**Figure 1**). Likewise, the incidence of MACEs were similar in patients undergoing PCI with RA followed by stent versus stent-only at 6 months (OR, 0.49; 95% CI, 0.21-1.17; P = 0.11), 9-12 months (OR, 0.84; 95% CI, 0.61-1.17; P = 0.31), and longer than 12 months (OR, 0.87; 95% CI, 0.24-3.09; P = 0.82).

TLR: According to **Figure 2**, there were 13 observational studies [2-8, 10, 12, 14, 15, 17, 18] and 5 RCTs [9, 11, 13, 16, 19] used for the quantitative analysis of TLR. Pooled effects showed a decreased TLR in patients treated with RA followed by stent (16.4%, 305/1,861) as compared to patients receiving stent-only (17.8%, 618/3,479) (OR, 0.69; 95% CI, 0.48-0.99; P = 0.04). Statistical heterogeneity was evident among these studies (P<0.00001, I^2 = 72%). However, the rates of TLR at 6 months (OR, 0.68; 95% CI, 0.42-1.10; P = 0.12), 9-12 months (OR, 0.82; 95% CI, 0.57-1.19; P = 0.30),

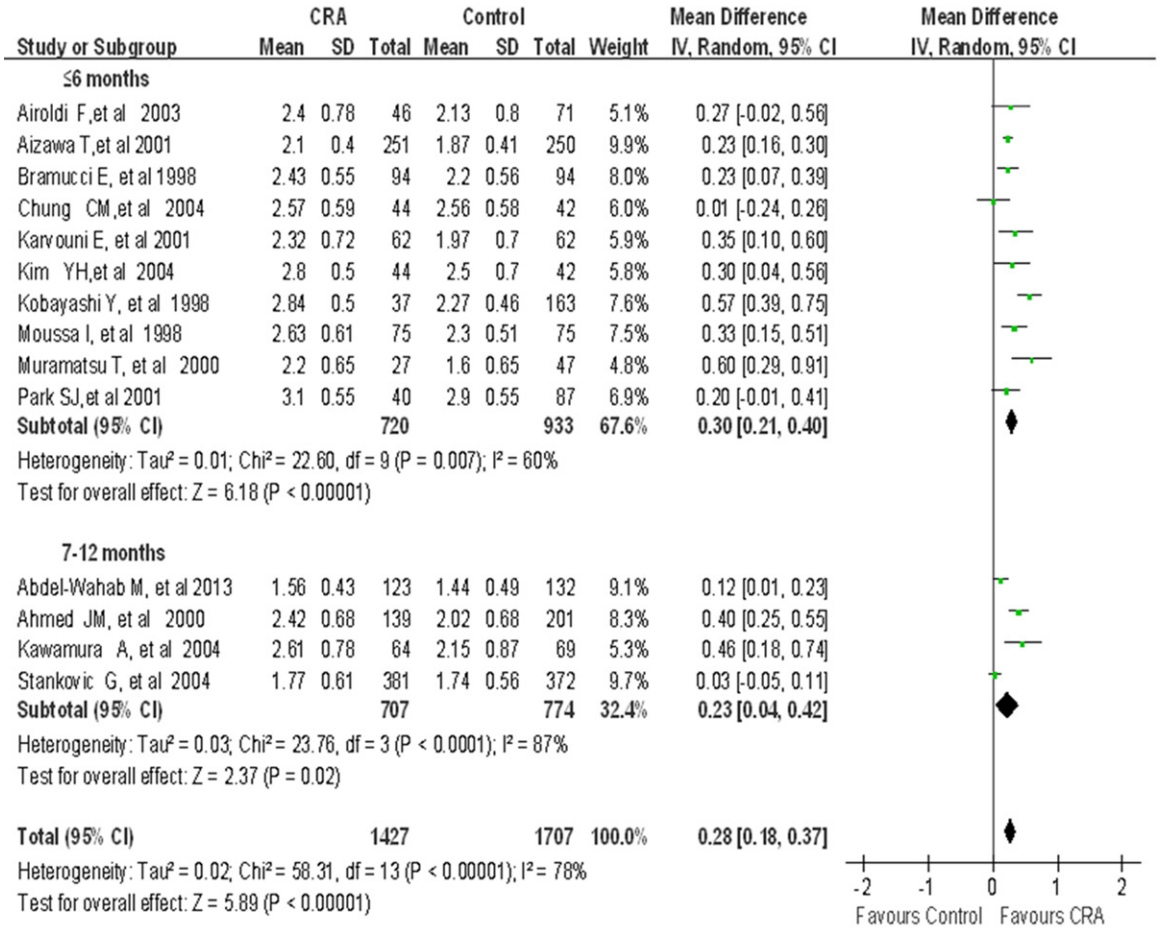

Figure 4. Comparison of rotational atherectomy combined with stent versus stent-only for the angiographic outcome f acute gain.

and longer than 12 months (OR, 0.53; 95% CI, 0.19-1.46; *P* = 0.22) showed no statistical difference between the two groups.

MI: As presented in **Figure 3**, 10 studies [4, 6-8, 10, 11-13, 15-19] were involved for analyzing MI. Among them, 3 studies reported the MI rates in both groups were zero [7, 8, 13]. The overall rates of MI in stent-only group were lower both in the total group (OR, 1.63; 95% CI, 1.15-2.31; *P* = 0.006; I^2 = 23%, P_{het} = 0.23) and longer than 12 months subgroup (OR, 1.97; 95% CI, 1.19-3.26; *P* = 0.008). Although there was no significant difference between the two groups for MI at 6 months (OR, 2.04; 95% CI, 0.76-5.50; *P* = 0.16) and 9-12 months (OR, 1.26; 95% CI, 0.73-2.17; *P* = 0.40).

Angiographic endpoints

Acute gain: Fourteen trials [2-14, 19] with 3,134 patients were included. The meta-analysis showed RA followed by stent strategy compared to stent-only was associated to a better acute gain (weighted mean difference (WMD), 0.28; 95% CI, 0.18-0.37; *P*<0.00001). Statistical heterogeneity was evident among these studies (*P*<0.00001, I^2 = 78%). Similar situations can be observed in either 6 months or less (WMD, 0.30; 95% CI, 0.21-0.40; *P*<0.00001) and 6-12 months (WMD, 0.23; 95% CI, 0.04-0.42; *P* = 0.002) subgroup (**Figure 4**).

Late lumen loss: A total of 11 trials [2, 4, 5, 7, 10-14, 18, 19] were selected for evaluating late lumen loss. In **Figure 5**, no statistical differences were detected in not only the total group (WMD, -0.03; 95% CI, -0.14 to 0.09; *P* = 0.65), but also the subgroups of less than 6 months (WMD, -0.10; 95% CI, -0.24 to 0.004; *P* = 0.16) and 6-12 months (WMD, 0.10; 95% CI, -0.02 to 0.22; *P* = 0.09) when comparing the late lumen loss of RA followed by stent and stent-only.

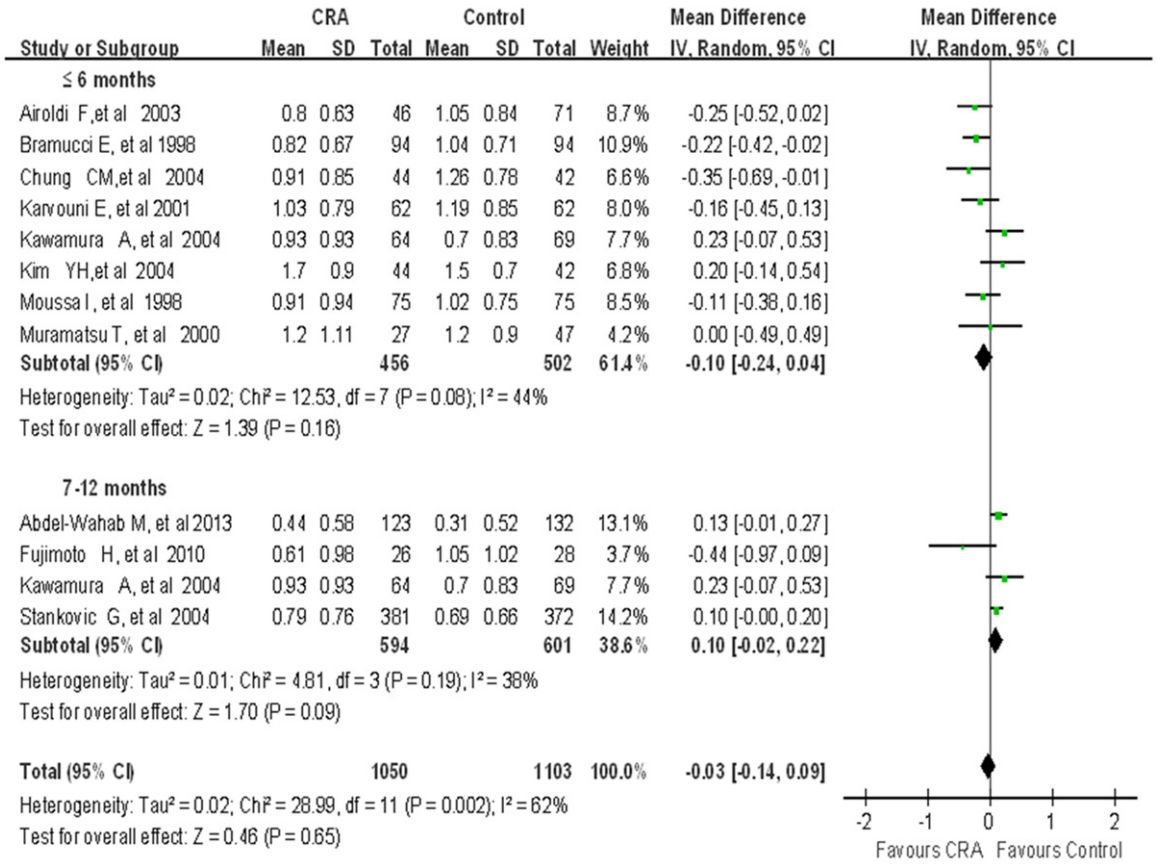

Figure 5. Comparison of rotational atherectomy combined with stent versus stent-only for the angiographic outcome of late lumen los.

Restenosis: According to **Figure 6**, 15 studies [2-5, 7-14, 16, 18, 19] were used for the quantitative analysis of restenosis. The combined approach of RA before stent compared to stent-only was associated to a significantly lower rate of restenosis in the total group (OR, 0.53; 95% CI, 0.38-0.76; *P* = 0.0004; I^2 = 65%, P_{het} = 0.0003). When separated into subgroups, RA followed by stent also decreased restenosis rates in the less than 6 months subgroup (OR, 0.47; 95% CI, 0.34-0.66; P<0.00001), but not in the 6-12 months subgroup (OR, 0.94; 95% CI, 0.50-1.79; P = 0.86).

Heterogeneity and subgroup analysis

Since significant heterogeneity across studies was found in this meta-analysis, heterogeneity analysis was performed by deselecting studies one by one. The results showed that no single study within each analysis seemed to be responsible for the significant heterogeneity (data not shown).

Furthermore, subgroup analysis based on study design was conducted. Subgroup analysis showed that there was no difference in the rate of MACEs and TLR and a better acute gain was found both in the RCTs and non-RCTs between the two groups. In addition, no statistical differences between the two groups for the rates of MI at RCTs, but difference exists in the non-RCTs subgroup. RA followed by stent strategy decreased late lumen loss and restenosis rates in the subgroup of non-RCTs, although this benefit was not found in the subgroup of RCTs (**Table 4**).

Publication bias

Since TLR data involving 18 studies, publication bias was performed for TLR data. Begg's test (P = 0.23) and Egger's test (P = 0.04) indicated the existence of potential publication bias. However, the trim-and-fill method indicated that no missing studies were needed to achieve a symmetrical funnel plot (**Figure 7**).

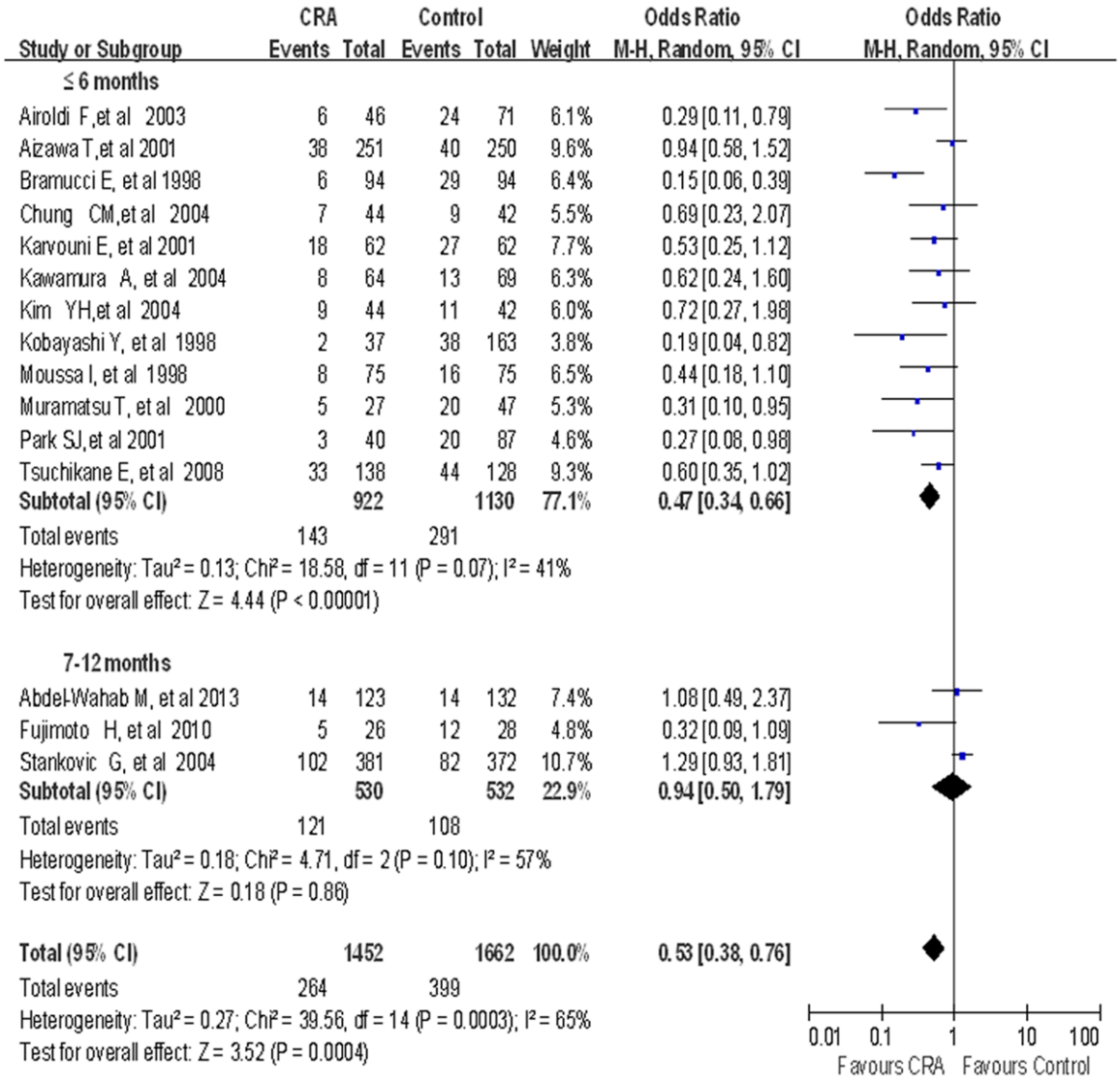

Figure 6. Comparison of rotational atherectomy combined with stent versus stent-only for the angiographic outcome of restenosis.

Discussion

The present meta-analysis based on currently available published RCTs and observational studies demonstrates that RA before stent is superior to stent alone with regard to TLR, better acute gain, and restenosis and this effect occurs despite a long follow-up period. However, a higher incidence of MI was observed in patients treated by RA followed by stent technique. No significant difference was evident for MACEs and late lumen loss between the RA followed by stent and stent-only groups.

Calcified coronary lesions showed a significant correlation with stent under expansion, restenosis, and procedural complications [1]. In the PCI era, effective treatment for heavily calcified coronary lesions remains a challenge. Studies from the bare-metal stent (BMS) era consistently demonstrated that RA prior to stent implantation reduced the rate of TLR, angiographic restenosis and have a large lumen gain [2-5]. However, in the current era of DES, it remains an unsolved problem whether routine RA combined with stent strategy could improve outcome. The present meta-analysis allows an evaluation of clinical and angiographic benefits and drawbacks associated with the comparison between RA before stent versus stent alone.

Table 4. Subgroup analyses of clinical and angiographic outcomes based on study design

	Study (Ref.)	OR	95% CI	*P* value	I^2 (%)
RCT					
MACEs	[11, 13, 16, 19]	0.85	0.61 to 1.18	0.33	0
TLR	[9, 11, 13, 16, 19]	0.77	0.56 to 1.06	0.11	32
MI	[11, 13, 16, 19]	1.32	0.74 to 2.36	0.35	0
Acute gain	[9, 11, 13, 19]	0.15	0.03 to 0.27	0.01	79
Late loss	[11, 13, 19]	0.12	0.04 to 0.19	0.004	0
Restenosis	[9, 11, 13, 16, 19]	0.95	0.70 to 1.29	0.74	36
NON-RCT					
MACEs	[4, 6-8, 10, 15, 17]	0.69	0.27 to 1.75	0.43	83
TLR	[2-8, 10, 12, 14, 15, 17, 18]	0.61	0.35 to 1.05	0.08	76
MI	[4, 6-8, 10, 12, 15, 17, 18]	1.86	1.20 to 2.87	0.005	36
Acute gain	[2-8, 10, 12, 14]	0.34	0.24 to 0.44	<0.00001	58
Late loss	[2, 4, 5, 7, 10, 12, 14, 18]	-0.15	-0.28 to -0.02	0.02	30
Restenosis	[2-5, 7, 8, 10, 12, 14, 18]	0.37	0.27 to 0.51	<0.00001	0

OR, odds ratio; CI, confidence interval; TLR, target lesion revascularization; MACEs, major adverse cardiovascular events; MI, myocardial infarction; NA, not available.

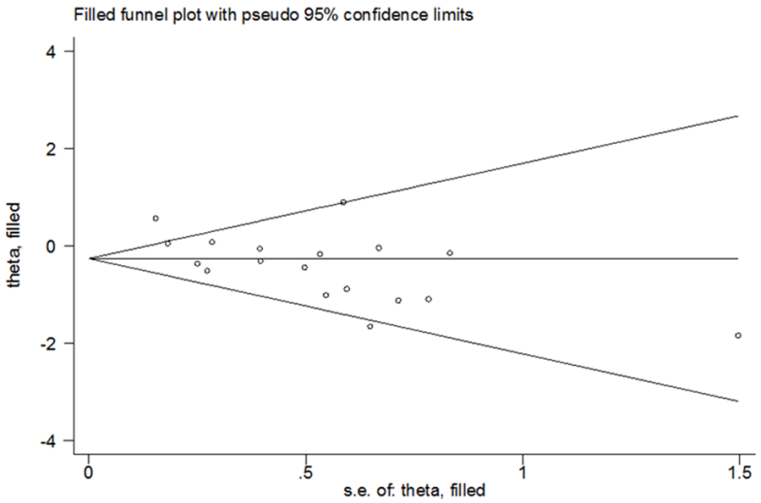

Figure 7. Funnel plot for target lesion revascularization comparing rotational atherectomy combined with stent versus stent-only. The trim-and-fill method suggests that no missing studies were needed to achieve a symmetrical funnel plot.

Clinical outcomes

In the present study, the incidence of cumulative MACEs was similar between the two strategy groups at scheduled clinic follow-up. This finding is consistent with most of the prior studies [6, 8, 13, 19]. However, there are some interesting observations in the individual clinical endpoints. In the present meta-analysis, there was a 31% reduction in the TLR with RA before stent strategy for calcified coronary lesions treatment. But the incidence of TLR in the follow-up period did not differ between the different strategy groups. And was relatively lower using RA combined with stent compared with that using stent alone in historical studies. In this meta-analysis, another major concern is of the risk of the increased MI with the RA before stent for calcified coronary lesions. Follow-up period sub analysis shows the incidence of MI occurred after 12 months. One possible reason may be that RA impaired vessel-wall healing and increased risk of very late stent thrombosis.

Angiographic outcomes

The risk of in-stent restenosis is a further point of interest when RA is used in calcified lesions. In the past, the authors also cautioned that delayed endothelial healing after the RA potentially increases the risk of in-stent restenosis [11, 22]. There is a theoretical risk that endothelial healing may be impaired after RA, thus predisposing to an increased risk of neointimal hyperplasia and in-stent restenosis. However, the use of RA before stent implantation in calcified coronary lesions was associated with a low

risk of in-stent restenosis was observed in our meta-analysis. This was further supported by the similar extent of late lumen loss between the two groups found in this meta-analysis. Subgroup analysis based on follow-up period also supported this finding. Late lumen loss, defined as the difference between the minimum lumen diameter (MLD) immediately after stenting and the MLD at 6 to 8 months follow-up. Late loss in luminal diameter reflects the time-related anatomical change of the lesions after angioplasty, and is an independent risk factor for restenosis after angioplasty [23, 24]. In addition, this meta-analysis demonstrated a better acute gain in the RA combined with stent group compared to the control group both in the overall pooled results and subgroup analyses. Taken together, these findings suggest that the angiographic outcome may be improved by RA followed by stent implantation strategy.

Comparison with previous meta-analysis

Our results were consistent with that of a similar meta-analysis by Niccoli G *et al*. [25]. Our meta-analysis yielded a similar overall reduction in the incidence of TLR and angiographic restenosis rate and a better acute lumen gain when RA plus stent group compared to the stent alone group. However, the present meta-analysis also has several distinguishing features. Firstly, we added 2 additional RCT and 4 additional observational studies and 1 additional clinical endpoint, MI. Secondly, we evaluate the longest available clinical and angiographic outcomes based on the different follow-up duration subgroup analysis. Thirdly, though we found there was no difference in the rate of MACEs and TLR and a better acute gain between the two groups both in the RCTs and non-RCTs. The rates of MI and late lumen loss difference exist in the non-RCTs subgroup.

Limitations

Our systematic review has limitations which should be noted. First, our study is based on study-level data and as such has the inherent limitations of the studies used. Second, 13 non-RCTs and 5 RCTs were included in our meta-analysis and the results of our meta-analysis may be affected by selection bias and confounders. Third, some heterogeneity was observed among the included studies, which was due primarily to the design of the included trials (most were non-RCTs) and the patient characteristics.

Conclusions

In conclusion, our meta-analysis suggests that RA followed by stent implantation is superior to stent alone in terms of TLR, better acute gain, and restenosis rates during long-term periods. But a higher MI risk existed in patients treated by RA combined with stent implantation strategy. Longer follow-up studies and more RCTs are needed to evaluate whether RA followed by stent implantation is better than stent-only in the treatment of calcified coronary lesions.

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Disclosure of conflict of interest

None.

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