Long-term Outcomes of Drug-eluting versus Bare-metal stent for ST-elevation Myocardial Infarction

Liping Wang, Hongyun Wang, Pingshuan Dong, Zhuanzhen Li, Yanyu Wang, Nana Duan, Yuwei Zhao, Shaoxin Wang

Department of Cardiology, the First Affiliated Hospital, Henan University of Science and Technology, Luoyang City, China

Abstract

Background: Long-term outcomes of drug-eluting stents (DES) versus bare-metal stents (BMS) in patients with ST-segment elevation myocardial infarction (STEMI) remain uncertain.

Objective: To investigate long-term outcomes of drug-eluting stents (DES) versus bare-metal stents (BMS) in patients with ST-segment elevation myocardial infarction (STEMI).

Methods: We performed search of MEDLINE, EMBASE, the Cochrane library, and ISI Web of Science (until February 2013) for randomized trials comparing more than 12-month efficacy or safety of DES with BMS in patients with STEMI. Pooled estimate was presented with risk ratio (RR) and its 95% confidence interval (CI) using random-effects model.

Results: Ten trials with 7,592 participants with STEMI were included. The overall results showed that there was no significant difference in the incidence of all-cause death and definite/probable stent thrombosis between DES and BMS at long-term follow-up. Patients receiving DES implantation appeared to have a lower 1-year incidence of recurrent myocardial infarction than those receiving BMS (RR = 0.75, 95% CI 0.56 to 1.00, p= 0.05). Moreover, the risk of target vessel revascularization (TVR) after receiving DES was consistently lowered during long-term observation (all p< 0.01). In subgroup analysis, the use of everolimus-eluting stents (EES) was associated with reduced risk of stent thrombosis in STEMI patients (RR = 0.37, p=0.02).

Conclusions: DES did not increase the risk of stent thrombosis in patients with STEMI compared with BMS. Moreover, the use of DES did lower long-term risk of repeat revascularization and might decrease the occurrence of reinfarction. (Arq Bras Cardiol. 2014; 102(6):529-538)

Keywords: Drug-eluting stents; Bare-metal stents; Acute myocardial infarction; Long-term outcomes; Meta-analysis.

Introduction

The use of bare-metal stents (BMS) has showed the benefit in reducing the risk of reocclusion of the ischemia-related artery and the need for repeat revascularization in ST-segment elevation myocardial infarction (STEMI) as compared with balloon angioplasty[1]. However, more than 20% subjects with STEMI who received BMS implantation during primary percutaneous coronary intervention suffered from in-stent restenosis[2]. Currently, drug-eluting stents (DES) are increasingly used for treatment of STEMI and remedy the above drawback of BMS[3,4].

However, concerns have arisen regarding a potentially higher risk of stent thrombosis with DES related to the reduced endothelialization and healing[5], especially in the setting of STEMI patients with the higher possible thrombotic coronary lesions[6]. The long-term follow-up of several pivotal studies showed an increased risk of stent thrombosis associated with DES implantation in STEMI subjects compared with BMS[7,8], but this result has not been confirmed by other studies[3,9]. Current clinical evidence based on registry studies and randomized controlled trials (RCTs) focusing on this issue delivering conflicting results. These inconsistent findings confused interventional cardiologists' stent selection decisions in these specific subjects. Initial meta-analyses showed the efficacy and safety of DES placement at short-term follow-up in the setting of STEMI[10,11], with no safety issues. However, the longer-term treatment effect of stent implantation on these high-risk patients remains uncertain. Therefore, here we performed a meta-analysis on basis of the available data from RCTs to elucidate the long-term clinical outcomes of DES versus BMS in patients with STEMI.

Methods

Eligible criteria

A study was included if 1) patients with STEMI were randomly assigned to DES (everolimus- [EES], zotarolimus-, sirolimu- [SES], or paclitaxe-eluting stent [PES]) versus BMS; 2) the data on

Mailing Address: Shaoxin Wang •
Department of Cardiology, The First Affiliated Hospital, Henan University of Science and Technology - Jinghua Road No.24, Luoyang city 471003, China.
Email: shaoxinwang1999@126.com
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efficacy or safety endpoints was available; 3) follow-up duration was no less than 12 months. We restricted our analyses to the DES approved by the US Food and Drug Administration (FDA). Trials would be excluded if the data on patient or procedural characteristics was not available, and post-hoc analyses of RCTs were also excluded.

Study identification

We systematically searched MEDLINE, EMBASE, the Cochrane library, and ISI Web of Science for the eligible trials (until July 2013) using the following terms: *everolimus-eluting stent, zotarolimus-eluting stent, drug-eluting stent, sirolimus-eluting stent, paclitaxel-eluting stent, bare-metal stent, uncoated stent, ST-segment elevation myocardial infarction, ST-segment elevation acute coronary syndrome*. We checked the reference lists of review articles, meta-analyses, and original studies identified by the electronic searches to find other eligible trials. The search was restricted to English-language literature.

Study enrollment, data collection, and quality assessment

Two investigators independently assessed trial eligibility using predefined eligibility criteria. The data, such as participant characteristics, lesion and procedural characteristics, and follow-up duration, were extracted. The information on clinical outcomes (e.g. all-cause death, recurrent myocardial infarction, target vessel revascularization [TVR], or definite/probable stent thrombosis) was also recorded independently. Any disagreements were resolved through consensus. The quality of the trials was assessed according to concealment of treatment allocation; blinding of patients, investigators, or clinical outcome assessors; and the proportion of patients with complete clinical follow-up[12]. Additionally, a numerical score between 0 and 5 was assigned as a measure of study design and reporting quality based on Jadad scale[13].

Statistical analyses

The pooling analyses were performed using Review Manager 5.1 software (Cochrane Collaboration, Copenhagen, Denmark). We pooled treatment effects and calculated risk ratios (RRs) with 95% confidence intervals (CI) for all end points by using random-effects model. Statistical homogeneity was quantified with the I^2 statistic with a scale of 0% to 100% (>75% represented very large between-study inconsistency)[14]. Subgroup analysis was performed to test the potential influence of clinical factors including the type of DES, time from pain to angioplasty, dual antiplatelet therapy duration, and the percentage of use of glycoprotein IIb/IIIa inhibitors. Overall estimates in subgroup analyses were calculated based on the longest observations when a trial reported follow-up findings at different time points. For verification of the robustness of the results, sensitivity analyses were conducted by omitting each trial at a time from analysis and then calculating overall estimates for the remaining studies. Publication bias among the enrolled studies was qualitatively assessed using funnel plot method. The significance level was set at $p<0.05$. This work was organized as the guidelines of Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)[15].

Results

Our initial search yielded 2,465 potential literature citations (Figure 1). Among them, 1,209 were excluded by removing duplicate literatures and through review of title. Abstracts from 1,256 articles were reviewed and an additional 1,181 articles were excluded, leaving 75 for full publication review. Thereafter 60 were excluded (31 non-RCTs; 15 for comparing clinical outcomes of various DES; 2 having no data on clinical characteristics; 12 for follow-up period less than 12 months). Finally, we identified 15 articles reporting 10 studies for analysis[3,4,16-28].

A total of 7,592 participants with STEMI in the 10 long-term trials were included (Table 1). Of them, 4,601 were randomly allocated to DES group and 2,991 to BMS group. Among the 10 trials, 9 were two arm trials (six for SES vs. BMS[16,18-21,23-26,28]; two for PES vs. BMS[17,22,27]; one for EES vs. BMS[3]) and the rest one was three arm trial (SES vs. PES vs. BMS)[4]. Seven trials reported 1-year follow-up clinical outcomes[3,4,19,20,22,24,26]; 3 reported 2-year data[4,17,24]; 4 reported 3-year date[16,18,25,28]; and 3 reported more than 4-year data[21,23,27]. The majority of participants were male and the mean age ranged from 59 years to 64 years. Total stent length per patient ranged from 19mm to 29mm. Dual antiplatelet therapy duration ranged from 3 months to 12 months, and the percentage of use of glycoprotein IIb/IIIa inhibitors was from 51.75% to 100% in the included studies. Additionally, the level of quality for each article was graded with a score of 3 to 4 according to the Jadad scale (Table 1).

The pooling analyses showed that there were no significant differences in the incidence of all-cause death (1-year follow-up: RR = 0.90, p= 0.45, I^2= 0%; 2-year: RR = 0.75, p= 0.16, I^2= 0%; 3-year: RR = 0.80, p= 0.27, I^2= 0%; >4-year: RR = 0.83, p= 0.28, I^2= 0%; Figure 2) and definite/probable stent thrombosis (1-year: RR = 0.79, p= 0.15, I^2= 0%; 2-year: RR = 0.91, p= 0.79, I^2= 0%; 3-year: RR = 1.25, p= 0.33, I^2= 0%; >4-year: RR = 1.00, p= 0.99, I^2= 0%; Figure 3) between DES and BMS regardless of follow-up duration in patients with STEMI. Moreover, DES seemed likely to reduce the 1-year occurrence of recurrent myocardial infarction (RR = 0.75, 95% CI 0.56 to 1.00, p= 0.05, I^2= 0%; Figure 4). However, the superiority of DES became nonsignificant with the prolongation of observation period (all p > 0.10; Figure 4). Notably, the risk of TVR in STEMI patients receiving DES placement was dramatically lowered compared with that receiving BMS during 1-year to 3-year follow-up (1-year follow-up: RR = 0.47, 95% CI 0.37 to 0.61, p< 0.001, I^2= 30%; 2-year: RR = 0.42, 95% CI 0.25 to 0.70, p< 0.001, I^2= 37%; 3-year: RR = 0.53, 95% CI 0.39 to 0.72, p< 0.001, I^2= 0%), and the favorable effect of DES remained almost constant up to the maximum observed follow-up of more than 4 years (RR = 0.57, 95% CI 0.42 to 0.76, p< 0.001, I^2= 0%; Figure 5).

In subgroup analyses, the second-generation DES, EES, might provide a benefit in lowering the risk of stent thrombosis in STEMI patients (RR = 0.37, 95% CI 0.15 to 0.87, p=0.02, Table 2), whereas both the first-generation SES and PES did not show the benefit compared with BMS (both p > 0.1, Table 2). Except for this, there were no significant influences of several important clinical factors, such as the type of DES, time from symptom to angioplasty, dual antiplatelet therapy duration,

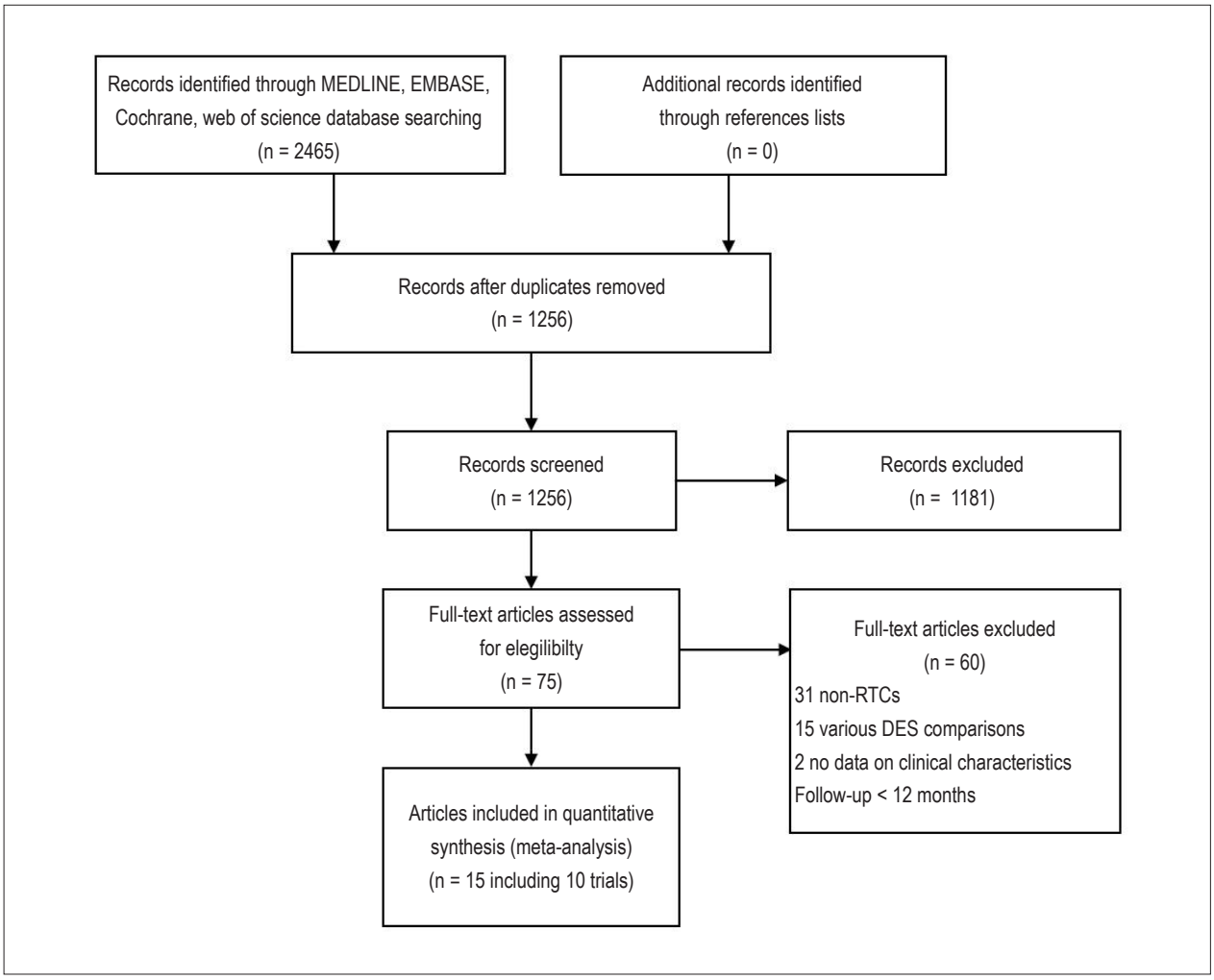

Figure 1 – *Flowchart of selection of studies for inclusion in meta-analysis. DES: drug-eluting stents; RCTs: randomized controlled trials*

and the percentage of use of glycoprotein IIb/IIIa inhibitors, on the beneficial effect of DES in TVR, with statistically significant differences (all $p < 0.01$, Table 2). Additionally, in sensitivity analysis omission of each trial one at a time from the analysis did not have any relevant influence on other overall results in the meta-analysis. Funnel plots were performed for all outcomes, and essential symmetry regarding overall TVR and stent thrombosis was found, which suggested that there was no publication bias in the meta-analysis.

Discussions

The present study revealed that no significant differences in the incidence of all-cause death and definite/probable stent thrombosis were shown between DES and BMS in patients with STEMI during long-term follow-up. Notably, the use of the second-generation DES, EES, offered a favorable effect on reducing the risk of stent thrombosis, whereas both SES and PES did not show the clinical benefit. Moreover, compared with BMS implantation, DES implantation seemed to be associated with reduced 1-year incidence of recurrent myocardial infarction, but the benefit did not maintain more than 2 years. Furthermore, DES showed a consistent benefit in lowering the risk of TVR during long-term observation.

Development of DES was primarily conceived to further improve clinical utility of coronary stent targeting on the potential drawback of BMS, mainly referring to the increased occurrence of in-stent restenosis. As a class of immunosuppressant and antiproliferative agent, sirolimus, paclitaxe, zotarolimus, or everolimus usually used to elute coronary stents exert potent inhibition of growth factor-induced proliferation of vascular intima and vessel smooth muscle cells[29]. The combination of anti-hyperplasia effect with potent mechanical support for lesion vessel wall in DES yielded a benefit in decreasing the need for repeat revascularization compared with BMS or balloon angioplasty alone during short-term follow-up[30]. Recently, concerns have been raised regarding the "late catch-up" phenomenon in DES, especially with "limus"-eluting stents, in unselected coronary artery diseases[31]. A study by Awata et al. using angioscopy showed that SES delayed reendothelialization with immature plaques and accelerated neointimal coverage

Table 1 – Baseline patient characteristics of randomized controlled trials included in the meta-analysis

First author, year	Study name	Comparisons	No. enrolled	Mean age	Male, %	Time from symptom to PCI, min	Target vessel, LAD/LCX/RCA, %	Stent length, mm	DAPT duration, m	Use of GP IIb/IIIa inhibitors, %	Follow-up, yrs	Jaded score
van der Hoeven BL 2008, Atary JZ 2010	MISSION	SES vs. BMS	158/152	59	77.7	189	54.8/15.7/29.5	26.4	12	99.6	1, 3	4
Dirksen MT 2008, Vink MA 2011	PASSION	PES vs. BMS	310/309	61	76	179	50/8.1/39.9	19	6	73.8	2, 5	4
Leibundgut G 2009	BASKET-AMI	SES vs. BMS	75/74	62.1	80	ND	—	39	6	67	3	3
Lorenzo ED 2009	PASEO	PES vs. SES vs. BMS	90/90/90	62.5	70	318	50.5/24.5/25	21	6	100	1, 2	4
Sabate M 2012	EXAMINATION	EES vs. BMS	751/747	61.1	83	within 48h	40.5/14.5/43.5	23	12	52.5	1	4
Spaulding C 2006, 2011	TYPHOON	SES vs. BMS	251/250	59.2	78.6	180	43.7/14.6/41.3	21.2	6	71.5	1, 4	4
Stone GW 2009	HORIZONS-AMI	PES vs. BMS	2257/749	59.6	76.5	223	41/15.5/43.5	29	6-12	51.75	1	4
Valgimigli M 2007, Tebaldi M 2009	STRATEGY	SES vs. BMS	87/88	63	73	180	45/19/36	23	3	100	1, 2, 5	4
Valgimigli M 2011	MULTISTRATEGY	SES vs. BMS	372/372	64	75.9	195	43.5/15.5/39.3	21	3	100	3	4
Menichelli M 2007, Violini R 2010	SESAMI	SES vs. BMS	160/160	62	80	240	49.7/12.8/37.5	18	12	74.9	1, 3	3

DAPT: dual antiplatelet therapy; EES: everolimus-eluting stents; LAD: left anterior descending artery; LCX: left circumflex artery; NA: not available; PES: paclitaxel-eluting stents; RCA: right coronary artery; STEMI: ST-segment elevation myocardial infarction; TIMI: Thrombolysis In Myocardial Infarction; SES: sirolimus-eluting stents.

at 2-year follow-up[32]. As a consequence, a significant increase in late luminal loss from 2- to 4-year follow-up was indicated[33]. A randomized trial demonstrated a lower luminal loss at 6 months with EES compared with PES. However, this initial advantage disappeared at 3-year follow-up[34], suggesting that delayed luminal loss might occur in DES. However, the profile of the unfavorable phenomenon in higher risk coronary artery diseases (e.g. STEMI) post DES implantation is now not well established. In the current study, a maintained clinical benefit of DES for more than 4 years in terms of reintervention in the previously instrumented artery with no excess of probable or definite stent thrombosis was identified in the current study. Conservatively, the beneficial result did not verify the presence of late catch-up with clinical significance in the setting of STEMI patients receiving DES treatment.

The propensity of stent thrombosis after DES implantation has raised safety concern in unselected coronary artery diseases[35] . However, to date we do not know that whether the thrombosis risk of DES is higher in STEMI patients with the higher possible thrombotic coronary lesions. The implantation of DES in ruptured plaques with a large necrotic core (the lesion substrate responsible for most cases of STEMI) might impair vascular healing responses, and potentially result in increased rates of stent thrombosis[36] . However, a previous meta-analysis comparing DES versus BMS for acute coronary syndromes did not show an evidence of significantly increased risk of stent thrombosis associated with DES implantation[37]. Similarly, the current study did not show the significant increase in fatal thrombotic evens and all-cause death associated with DES placement in STEMI patients. Even in a special class of DES, mainly referring to EES, a favorable effect in reducing the risk of stent thrombosis was shown at long-term follow-up. The finding was consistent with the result from a previous large-scale meta-analysis in unselected coronary artery diseases, indicating that EES treatment had the lower rate of stent thrombosis within 2 years of stent implantation than BMS[38]. Causally, STEMI was characterized by the more possible thrombotic coronary lesions than non-ST segment elevation acute coronary syndrome or stable coronary artery diseases. As thus, we presumed that, in terms of lowering the risk of stent thrombosis, EES might have the more superiority in patients with higher possible thrombotic lesions. Additionally, a favorable tendency toward reduce the risk of recurrent myocardial infarction was achieved in DES treatment group in the first year follow-up, but the potential benefit did not maintain during the longer-term observation. It was notable that the trend of reinfarction related to DES placement was presented substantially consistent with that of stent thrombosis, the risk of which appeared to be lower at 1-year follow-up. The potential benefit of DES in lowering the rate of reinfarction might partially result from their favorable trend to reducing the risk of stent thrombosis.

Methodologically, the use of random-effect model, no publication bias, and relatively low statistical heterogeneities among the included trials corrected the inherent drawback and provided reassurance for making a robust conclusion. Moreover, sensitivity analyses further confirmed the credibility

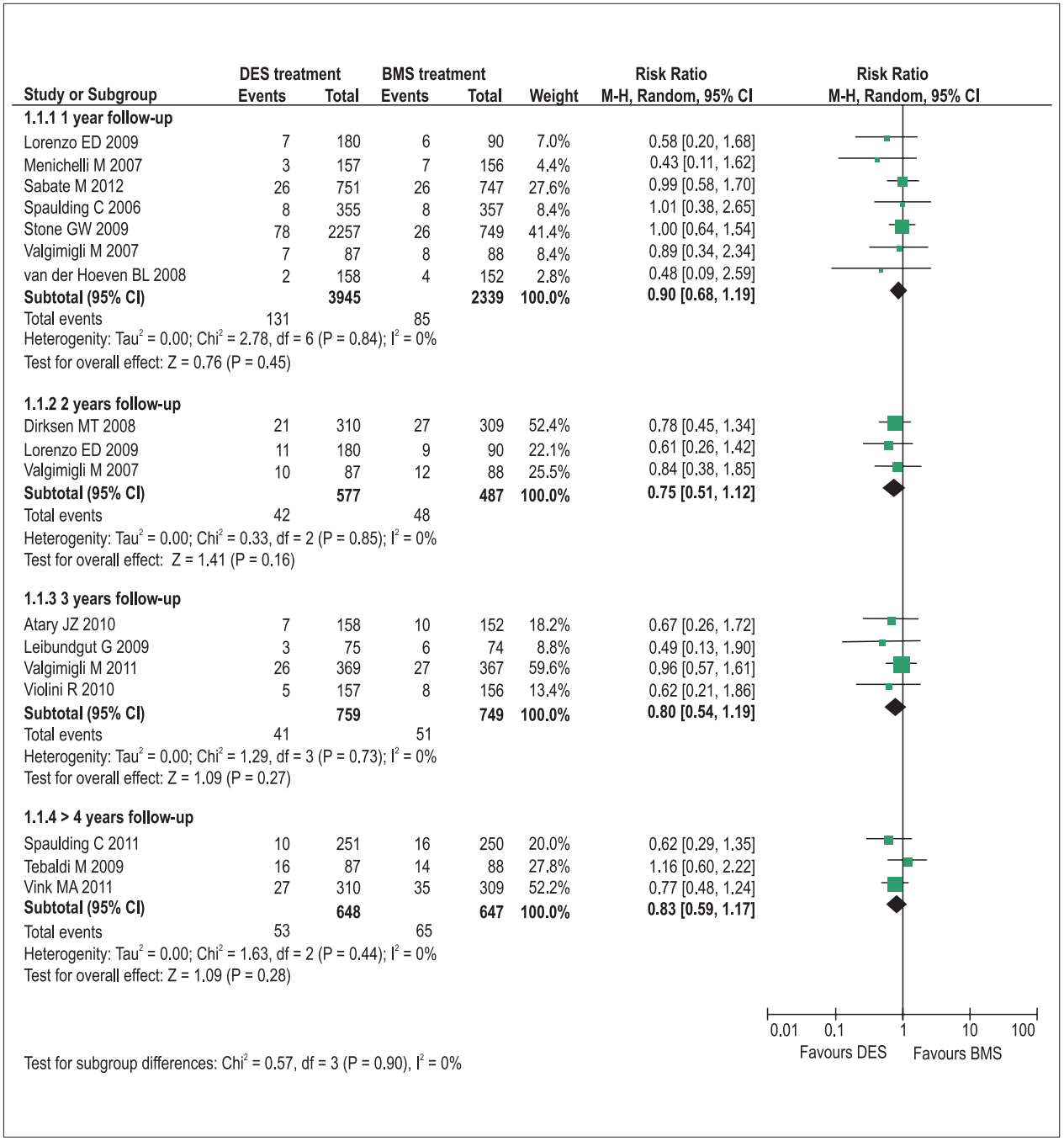

Figure 2 – *Pooled risk ratios of DES versus BMS for all-cause mortality. BMS: bare-metal stents; CI: confidence intervals; DES: drug-eluting stents; M–H: Mantel-Haenszel.*

of the meta-analysis estimates. However, it was worthwhile notable that this meta-analysis investigated the long-term clinical outcomes of DES versus BMS in patients with STEMI, the results of which cannot be automatically extrapolated to non-ST-segment elevation acute coronary syndrome. In addition, the power in subgroup analysis on ≥2-year follow-up data might be restricted by the limited study number, and the conclusions should be made carefully. Therefore, more studies with longer-term observation are required to further verify the findings and conclusions in the subgroup analyses of the current study.

Conclusions

This present study has identified the persistent benefit of DES on reducing the need for repeat revascularization in patients with STEMI at long-term follow-up. Although DES did not offer a benefit in reducing all-cause mortality

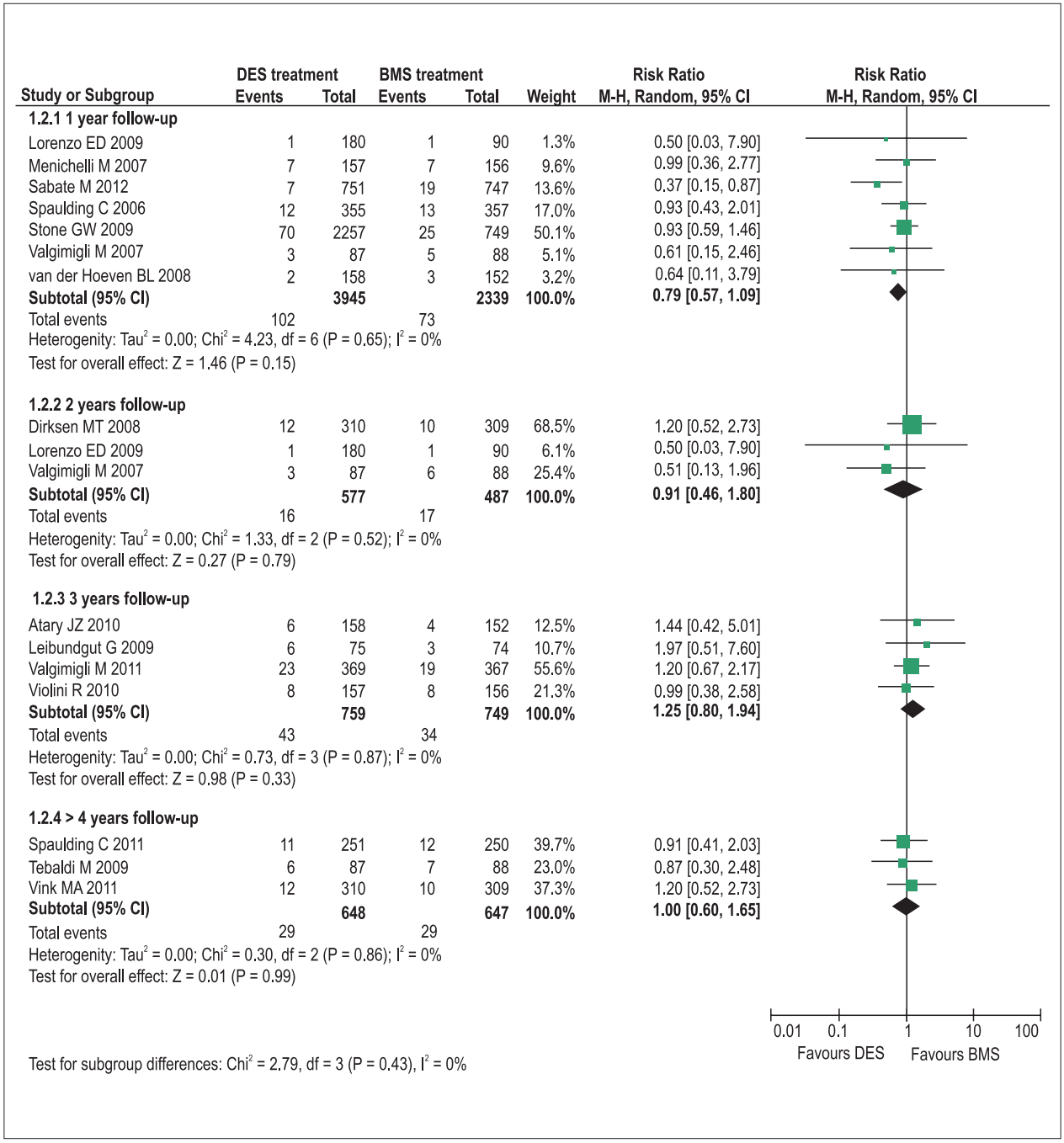

Figure 3 – *Pooled risk ratios of DES versus BMS for definite or probable stent thrombosis. BMS: bare-metal stents; CI: confidence intervals; DES: drug-eluting stents; M–H: Mantel-Haenszel.*

compared with BMS, the procedure did not increase the risk of stent thrombosis, and even EES might markedly decrease the malignant clinical occurrence in these specific patients with the higher possible thrombotic coronary lesions. In addition, DES seems to be as safe as BMS, without evidence of any increased long-term risk of all-cause death and recurrent myocardial infarction. The current study, a meta-analysis based on the newest available data from RCTs comparing DES versus BMS in patients with STEMI, offers important insights into the relative safety and efficacy of DES.

Study or Subgroup	DES treatment Events	Total	BMS treatment Events	Total	Weight	Risk Ratio M-H, Random, 95% CI
1.3.1 1 year follow-up						
Lorenzo ED 2009	7	180	6	90	7.2%	0.58 [0.20, 1.68]
Menichelli M 2007	3	157	3	156	3.2%	0.99 [0.20, 4.85]
Sabate M 2012	10	751	15	747	12.9%	0.66 [0.30, 1.47]
Spaulding C 2006	4	355	5	357	4.8%	0.80 [0.22, 2.97]
Stone GW 2009	81	2257	33	749	51.6%	0.81 [0.55, 1.21]
Valgimigli M 2007	6	87	8	88	7.9%	0.76 [0.27, 2.10]
van der Hoeven BL 2008	9	158	14	152	12.4%	0.62 [0.28, 1.39]
Subtotal (95% CI)		**3945**		**2339**	**100.0%**	**0.75 [0.56, 1.00]**
Total events	120		84			
Heterogenity: $Tau^2 = 0.00$; $Chi^2 = 0.83$, df = 6 (P = 0.99); $I^2 = 0\%$						
Test for overall effect: Z = 1.99 (P = 0.05)						
1.3.2 2 years follow-up						
Dirksen MT 2008	9	310	7	309	29.1%	1.28 [0.48, 3.40]
Lorenzo ED 2009	11	180	10	90	41.4%	0.55 [0.24, 1.25]
Valgimigli M 2007	7	87	8	88	29.4%	0.89 [0.34, 2.34]
Subtotal (95% CI)		**577**		**487**	**100.0%**	**0.81 [0.48, 1.37]**
Total events	27		25			
Heterogenity: $Tau^2 = 0.00$; $Chi^2 = 1.75$, df = 2 (P = 0.42); $I^2 = 0\%$						
Test for overall effect: Z = 0.79 (P = 0.43)						
1.3.3 3 years follow-up						
Atary JZ 2010	12	158	17	152	54.9%	0.68 [0.34, 1.37]
Leibundgut G 2009	9	75	5	74	28.0%	1.78 [0.62, 5.05]
Violini R 2010	4	157	4	156	17.1%	0.99 [0.25, 3.90]
Subtotal (95% CI)		**390**		**382**	**100.0%**	**0.95 [0.53, 1.70]**
Total events	25		26			
Heterogenity: $Tau^2 = 0.03$; $Chi^2 = 2.25$, df = 2 (P = 0.33); $I^2 = 11\%$						
Test for overall effect: Z = 0.18 (P = 0.86)						
1.3.4 > 4 years follow-up						
Spaulding C 2011	12	251	10	250	32.6%	1.20 [0.53, 2.72]
Tebaldi M 2009	7	87	8	88	23.3%	0.89 [0.34, 2.34]
Vink MA 2011	19	310	12	309	44.1%	1.58 [0.78, 3.20]
Subtotal (95% CI)		**648**		**647**	**100.0%**	**1.26 [0.79, 2.01]**
Total events	38		30			
Heterogenity: $Tau^2 = 0.00$; $Chi^2 = 0.92$, df = 2 (P = 0.63); $I^2 = 0\%$						
Test for overall effect: Z = 0.97 (P = 0.33)						
Test for subgroup differences: $Chi^2 = 3.62$, df = 3 (P = 0.31), $I^2 = 17.2\%$						

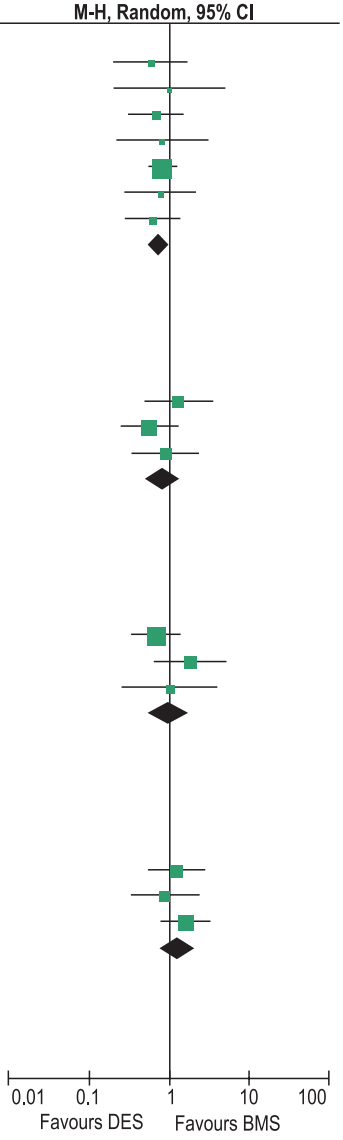

Figure 4 – *Pooled risk ratios of DES versus BMS for recurrent myocardial infarction. BMS: bare-metal stents; CI: confidence intervals; DES: drug-eluting stents; M–H: Mantel-Haenszel.*

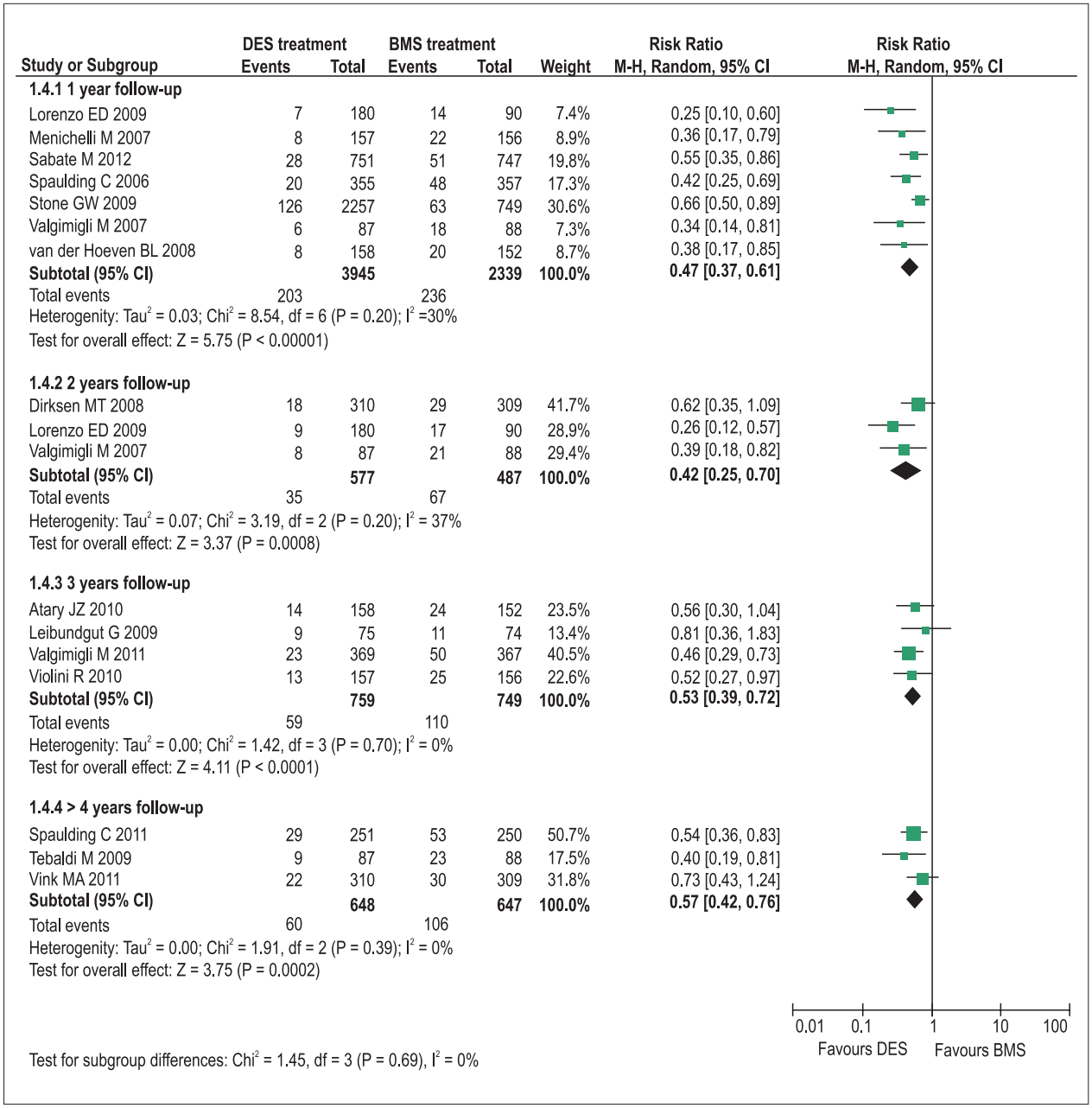

Figure 5 – *Pooled risk ratios of DES versus BMS for target vessel revascularization. BMS: bare-metal stents; CI: confidence intervals; DES: drug-eluting stents; M–H: Mantel-Haenszel.*

Table 2 – Subgroup analyses on target vessel revascularization and in-stent thrombosis

Subgroups	No. of patients	TVR		Stent thrombosis	
		RR (95% CI)	*p value*	RR (95% CI)	*P* value
SES	2364	0.50 [0.40, 0.63]	< 0.001	1.12 [0.78, 1.60]	0.54
PES	3805	0.62 [0.44, 0.88]	0.007	0.98 [0.67, 1.46]	0.94
EES	1498	0.55 [0.35, 0.86]	0.008	0.37 [0.15, 0.87]	0.02
Pain to angioplasty ≤ 3h	1295	0.57 [0.42, 0.76]	0.0002	1.00 [0.60, 1.65]	0.99
Pain to angioplasty > 3h	6133	0.54 [0.44, 0.67]	< 0.001	0.90 [0.63, 1.28]	0.55
DAPT duration ≤ 6 m	2450	0.51 [0.39, 0.67]	< 0.001	1.11 [0.77, 1.60]	0.56
DAPT duration > 6 m	5127	0.60 [0.49, 0.75]	< 0.001	0.81 [0.49, 1.33]	0.40
Use of GP IIb/IIIa inhibitors ≥ 90%	1491	0.43 [0.32, 0.58]	< 0.001	1.13 [0.71, 1.80]	0.61
Use of GP IIb/IIIa inhibitors < 90%	6086	0.62 [0.52, 0.74]	< 0.001	0.89 [0.63, 1.27]	0.52

CI: confidence interval; DAPT: dual antiplatelet therapy; EES: everolimus-eluting stents; GP: glycoprotein; PES: paclitaxel-eluting stents; RR: risk ratios; SES: sirolimus-eluting stents; TVR: target vessel revascularization.

Author contributions

Conception and design of the research: Wang S; Acquisition of data: Wang L, Wang H; Analysis and interpretation of the data: Wang L, Wang H, Li Z, Wang Y; Obtaining financing: Dong P; Writing of the manuscript: Wang L, Wang H, Wang Y; Critical revision of the manuscript for intellectual content: Dong P, Duan N, Zhao Y, Wang S.

Potential Conflict of Interest

No potential conflict of interest relevant to this article was reported.

Sources of Funding

There were no external funding sources for this study.

Study Association

This study is not associated with any thesis or dissertation work.

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