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ORIGINAL ARTICLE

Comparison of clinical outcomes between intravascular ultrasound-guided and angiography-guided drug-eluting stent implantation: A meta-analysis of randomised control trials and systematic review

Yu-Ying Tan[1] | Xia-Xia Man[2] | Ling-Yun Liu[3] | Hui Xu[1]

[1]Department of Echocardiography, The First Hospital of Jilin University, Changchun, China

[2]Department of Gynecologic Oncology, The First Hospital of Jilin University, Changchun, China

[3]Department of Andrology, The First Hospital of Jilin University, Changchun, China

Correspondence
Hui Xu, Department of Echocardiography, The First Hospital of Jilin University, No. 71 Xinmin Street, Changchun, Jilin 130012, China.
Email: xuhuixhxh@sohu.com

This systematic review was designed to evaluate the overall efficacy of angiography-guided drug-eluting stent (DES) implantation vs intravascular ultrasound-guided (IVUS) implantation for percutaneous coronary intervention. The electronic databases CENTRAL, PubMed, Cochrane, and EMBASE were searched for systematic reviews to investigate angiography-guided and IVUS-guided DES implantation. We measured the following six parameters in each patient: cardiovascular death, stent thrombosis, target lesion revascularisation (TLR), myocardial infarction (MI), major adverse cardiac events (MACEs), and all-cause death. Twelve studies involving 6268 subjects were included, with 2984 receiving IVUS-guided DES implantation and 3284 using angiography-guided DES implantation. With regard to MACEs, TLR, MI, cardiovascular death, and all-cause death, the IVUS-guided DES implantation group had remarkably improved clinical outcomes. However, there was no significant statistical difference in stent thrombosis between the two groups. Dramatic decrease in MACEs through IVUS guidance was presented by trial sequential analysis. Remarkably improved clinical outcomes, including MACEs, cardiovascular death, all-cause death, and TLR, were identified through IVUS-guided DES implantation in comparison with angiography-guided DES implantation. Nonetheless, the effect on stent thrombosis and MI required further confirmation. In this meta-analysis, eligible randomised clinical trials were warranted to verify the findings and to determine the beneficial effect of IVUS guidance for patients.

KEYWORDS

angiography, drug-eluting stent, intravascular ultrasound, meta-analysis, percutaneous coronary intervention

1 | INTRODUCTION

Drug-eluting stents (DES) have led to remarkable advances in cardiology and have significantly improved the outcome of percutaneous coronary intervention (PCI) and are superior to bare stents.[1] However, the incidence of stent restenosis and in-stent restenosis are still problems to be solved, especially in the treatment of complex lesions. Coronary angiography has remained a standard scheme to guide DES placement, but because of the projection angle and two-dimensional plane judgement, it often leads to inaccurate evaluation of the severity of coronary stenosis, plaque structure, and stent placement.[2] Intravascular ultrasound (IVUS), as an invasive detection technique, can provide more accurate information about coronary anatomy and plaque size, position, nature, and other characteristics; accurately judge

the extent and range of vascular lesions; ensure that the appropriate diameter and length of stent is chosen; and optimise coronary stent placement. IVUS can also evaluate stent size, position, shape, wall level, and interlayer in stent implantation to avoid stent dilation, improper wall sticking, and incomplete coverage of lesions or excessive dilation of the stent, thus decreasing the risk of stent restenosis and thrombosis formation.[3–5]

Current guidelines have recommended the use of IVUS for selected patients to optimise stent implantation (Class of recommendation IIa, Level of evidence B),[6,7] but the evidence was based on data from observational studies and bare stent eras. At present, DES is widely used in clinical practice, so stronger evidence is needed to support the application of IVUS in PCI. Because of the different results of the related clinical randomised controlled trials (RCTs), it is necessary to use meta-analysis for comprehensive evaluation to provide more effective evidence for choosing the rational guidance strategy for DES implantation.

Key Messages

- efficacy of angiography-guided drug-eluting stent (DES) implantation vs intravascular ultrasound (IVUS) for percutaneous coronary intervention was evaluated
- electronic databases were searched, and five parameters were measured
- remarkably improved clinical outcomes, including major adverse cardiac event, cardiovascular death, all-cause death and target lesion revascularisation, had been identified through IVUS-guided DES implantation
- IVUS-guided DES implantation on stent thrombosis and myocardial infarction required further confirmation

2 | MATERIALS AND METHODS

2.1 | Search strategy

We performed the current meta-analysis based on the Cochrane Handbook for Systematic Reviews of Interventions[8] and Preferred Reporting Items for Systematic Reviews and Meta-analyses guidelines.[9] We conducted a systematic screening process using the CENTRAL, PubMed, EMBASE, and Cochrane Database of Systematic Reviews from their inception to January 2018 based on the following MeSH terms and free key words: "percutaneous coronary intervention," "IVUS," "intravascular ultrasound," "angiography," and "drug-eluting stent." All relevant publications were identified without language restrictions, in which we identified full-text papers from reference materials for further evaluation.

2.2 | Inclusion criteria

Articles that were related to the following inclusion criteria were included in this analysis: (a) patients were clinically diagnosed with complex coronary artery lesions and underwent PCI using DES; (b) trials compared angiography-guided and IVUS-guided implantation; (c) more than one of the following parameters were mentioned in studies: stent thrombosis, cardiovascular death, myocardial infarction (MI), major adverse cardiac events (MACEs), target lesion revascularisation (TLR), and all-cause death; and (d) RCTs. Studies were excluded using the following exclusion criteria: (a) trials without a control group; (b) the reported data were clearly erroneous or incomplete and did not provide research outcomes; (c) observational studies or case reports; and (d) duplicated publications.

2.3 | Risk-of-bias assessments

The risk of bias was evaluated in each mentioned study based on Cochrane handbook version 5.1.0 for Systematic Reviews by Cochrane Collaboration. Study quality was evaluated, including allocation concealment, blinding of outcome assessment, blinding of participants and personnel, incomplete outcome data, random sequence generation, selective reporting, and other biases. Each entry was then classified as "high risk," "unclear risk," and "low risk."

2.4 | Data selection and extraction

After the screening process, studies were then assigned to certain topic(s). Using Thomson Research Software (EndNote X4, Microsoft, Redmond, Washington), we extracted relevant data for accuracy assessment. Any unclear information should be with more details of original articles. "Excluded (reason)," "Pending," and "Included" were included in the "notes" column. We retracted "Pending" articles from the references.

A self-designed data extraction form was used to independently extract contents by two researchers, including lead author, year of publication, participant characteristics, clinical stage of cancer, histological type, tumour size, treatment measures, outcomes, effect indicators, and follow-up duration. The literature screening process, data extraction, and quality evaluation process were performed separately by two reviewers. In case of disagreement, a third investigator was asked to help resolve the disagreement through discussion.

2.5 | Statistical analysis

The Review Manager Software (RevMan5.3, Microsoft, Redmond, Washington) was used for statistical analysis. Risk ratios (RR) and its 95% confidence interval (CI) were utilised for binary data and effect size in the meta-analysis. A χ^2 test was used to assess the significance of heterogeneity, and the degree of heterogeneity was then examined using the I^2 statistic. The fixed-effects model was used if the assessment of heterogeneity was insignificant ($P > 0.1$, $I^2 \leq 50\%$). If the source

of heterogeneity was uncertain, we used the random-effects model for further analysis.

2.6 | Trial sequential analysis

Trial sequential analysis (TSA) is a method for estimating sample size, which can adjust random errors and calculate the sample size through the TSA 0.9 Beta (available at http://www.ctu.dk/tsa). We estimated a diversity-adjusted required information size, which consisted of type power = 80%, *I* error $\alpha = 5\%$, and two-sided testing. The hypothesis was that 25% relative reduction could be achieved through IVUS guidance in the risk of MACEs, and in the angiography-guided group, there was a 10% anticipated event rate for MACEs. A graph of the cumulative *Z* curve presented the major results, and the boundaries in this graph were then determined by the O'Brien-Fleming α-spending function for final non-inferiority, inferiority, or superiority.

3 | RESULTS

3.1 | Study selection process

A total, 928 articles were identified initially. After 87 duplicates were removed, 804 irrelevant citations were further excluded based on the review of titles and abstracts. During full-text reading of the 37 included articles, 25 articles were then excluded. Finally, a total of 12 studies[10–21] published between 2010 and 2017 were assessed for eligibility in the meta-analysis (Figure 1).

3.2 | Quality assessment

Six[10–12,14,15,19] studies described random sequence generation using web-based systems, while three studies[13,18,21] just reported randomised trials without randomisation description; two studies[17,20] of random grouping method were assessed as a high risk of bias. Blinded methods were either used in participants or intervention providers in four trials. Most trials had comparable baseline clinical characteristics except one trial,[20] which had a statistically significant difference when comparing the two groups for current smokers. Blinding of outcome assessment was independent in all studies. None of the included studies had selective reporting or incomplete reporting. Three studies[10,12,14] were of high methodological quality, seven[11,13,15,16,18,19,21] of moderate quality, and the remaining two studies[17,20] of low quality. Figures 2 and 3 present the summary of the quality assessment process.

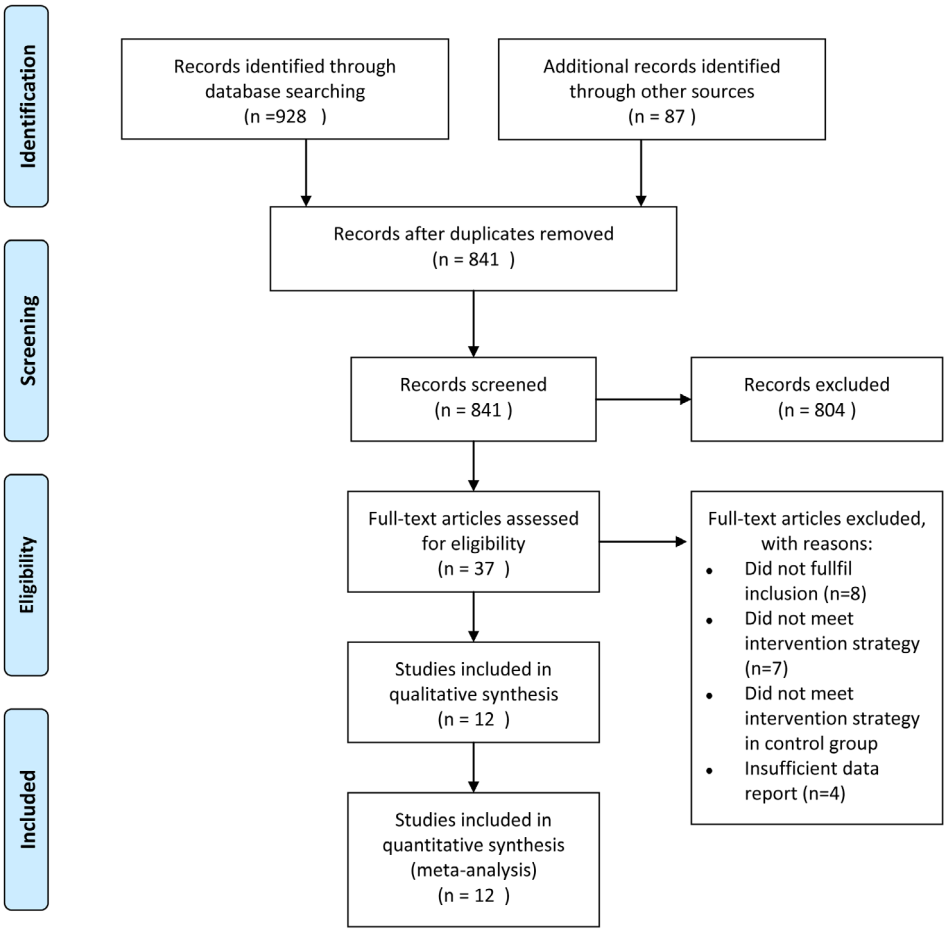

FIGURE 1 Flow diagram of study searching strategy

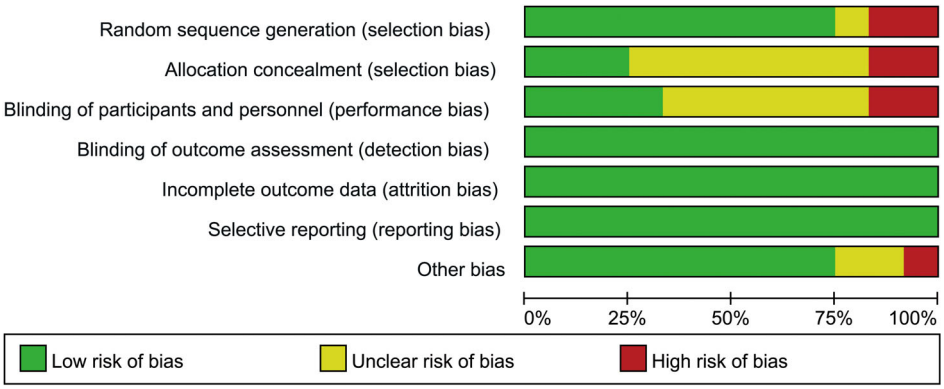

FIGURE 2 Quality assessment summary for included studies

3.3 | Characteristics of study selection

A total of 6268 patients were included in this meta-analysis, including 2984 receiving IVUS-guided DES implantation and 3284 using angiography-guided DES implantation. Studies included patients with complex lesions, such as long lesions (implanted stent ≥28 mm in length), left main lesions, chronic total occlusion, or small vascular lesions. Among those patients, follow-up duration varied from 30 days to 60 months, sample sizes from 84 to 1899, and mean ages from 50 to 80 years. No significant statistical difference was observed between the two groups in baseline characteristics such as diabetes, smoking status, and hypertension. Intervention strategies were similar among most of the trials. The major characteristics of the included studies are depicted in Table 1.

4 | OUTCOMES AND SYNTHESIS OF RESULTS

4.1 | Effects of interventions for early cervical cancer

4.1.1 | Major adverse cardiac events

Eleven studies[10–19,21] reported MACEs, including a total of 4369 patients (2098 in the angiography-guided PCI group and 2271 in the IVUS-guided PCI group). There was no statistical between-study heterogeneity in the RR of studies ($P = 0.26$, $I^2 = 19\%$); therefore, we used the fixed-effects model for pooling the data. As displayed in Figure 4, the pooled estimates of effect sizes showed significant statistical difference in MACE between the two groups (RR = 0.66, 95% CI [0.56, 0.78], $P < 0.0001$).

4.1.2 | Cardiovascular death

Nine studies[11,12,14–16,18–21] reported cardiovascular death, including a total of 5077 patients (2754 in the angiography-guided PCI group and 2323 in the IVUS-guided PCI group). There was no statistical between-study heterogeneity in RR of studies ($P = 0.79$, $I^2 = 0\%$), in which we utilised the fixed-effects model for pooling

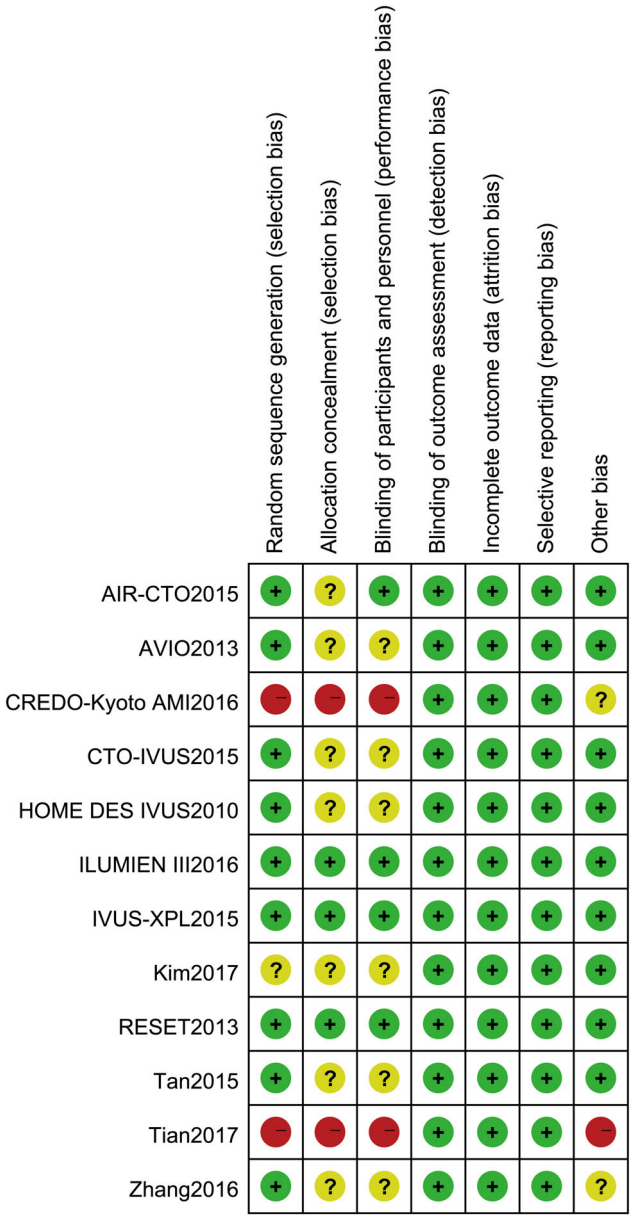

FIGURE 3 Methodological quality assessment for each included study; +, low risk of bias; –, high risk of bias; ?, unclear risk of bias

TABLE 1 Characteristics of the included studies

Author, y	Centre	Lesion characteristics	Procedures	Sample size/male	Patients baseline characteristics				Follow-up	Outcome measures
					Mean age	Diabetes	Smoker	Hypertension		
ILUMIEN III, 2016[10]	Multicentre	Complex lesions	IVUS	146/107	66 (61-72)	55 (38%)	19 (13%)	113 (77%)	12 mo	①③④⑤
			Angiography	146/107	67 (56-74)	42 (29%)	35 (24%)	109 (75%)		
AVIO, 2013[11]	Multicentre	Complex lesions	IVUS	142/117	63.9 ± 10.9	34 (23.9%)	49 (34.5%)	100 (70.4%)	24 mo	①②③④⑤
			Angiography	142/109	63.6 ± 11.0	38 (26.8%)	44 (31.0%)	109 (76.8%)		
IVUS-XPL, 2015[12]	Multicentre	Long lesions	IVUS	700/483	64 ± 9	250 (36%)	155 (22%)	454 (65%)	12 mo	①②③⑤
			Angiography	700/481	64 ± 9	256 (37%)	181 (26%)	444 (63%)		
HOMEDESIVUS, 2010[13]	Single-centre	Complex lesions	IVUS	105/73	59.4 ± 13	44 (42%)	42 (40%)	70 (67%)	18 mo	①③④⑤
			Angiography	105/71	60.2 ± 11	47 (45%)	37 (35%)	75 (71%)		
RESET, 2013[14]	Multicentre	Long lesions	IVUS	269/177	62.8 ± 9.3	85(31.6%)	58(21.6%)	165(61.3%)	12 mo	①②③④⑤
			Angiography	274/150	64.3 ± 8.7	82(29.9%)	47(17.2%)	178 (65.8%)		
CTO-IVUS, 2015[15]	Multicentre	Chronic total occlusion	IVUS	201/162	61.0 ± 11.1	70 (34.8%)	71 (35.3%)	126 (62.7%)	12 mo	①②③④⑤
			Angiography	201/162	61.4 ± 10.1	68 (33.8%)	69 (34.3%)	128 (63.7%)		
Kim, 2017[16]	Single-centre	Left main lesions	IVUS	122/95	62.1 ± 10.6	47 (38.5%)	36 (29.5%)	75 (61.5%)	30 d	①②③④⑤
			Angiography	74/53	64.8 ± 11.3	33 (44.6%)	21 (28.4%)	54 (73%)		
CREDO-Kyot AMI, 2015[17]	Multicentre	Acute myocardial infarction	IVUS	368	NR	NR	NR	NR	60 mo	①③④⑤⑥
			Angiography	237	NR	NR	NR	NR		
Tan, 2015[18]	Single-centre	Unprotected left main lesions	IVUS	61/38	76.5 ± 5.0	21 (34.4%)	27 (44.3%)	25 (41.0%)	24 mo	①②③④
			Angiography	62/43	75.9 ± 3.5	18 (29.5%)	29 (46.8%)	29 (46.8%)		
AIR-CTO, 2015[19]	Multicentre	Chronic total occlusion	IVUS	115/89	NR	35 (30%)	45 (39%)	86 (75%)	12 mo	①②③④⑤⑥
			Angiography	115/80	NR	31 (27%)	45 (39%)	81 (70%)		
Tian, 2017[20]	Single-centre	Unprotected left main lesions	IVUS	713/576	59.6 ± 10.9	173 (24.3%)	256 (35.9%)	400 (56.1%)	12 mo	②③④⑤⑥
			Angiography	1186/920	60.0 ± 10.2	314 (26.5%)	316 (26.6%)	654 (55.1%)		
Zhang, 2016[21]	Single-centre	Small vascular lesions	IVUS	42/21	63.2 ± 8.0	NR	22 (52.4%)	27 (64.3%)	12 mo	①②③
			Angiography	42/25	60.1 ± 9.4	NR	22 (52.4%)	25 (59.5%)		

Abbreviations: IVUS, intravascular ultrasound-guided; NR, not report.
Outcome measures: ① major adverse cardiac events, ② cardiovascular death, ③ myocardial infarction, ④ target lesion revascularisation, ⑤ stent thrombosis, ⑥ all-cause death.

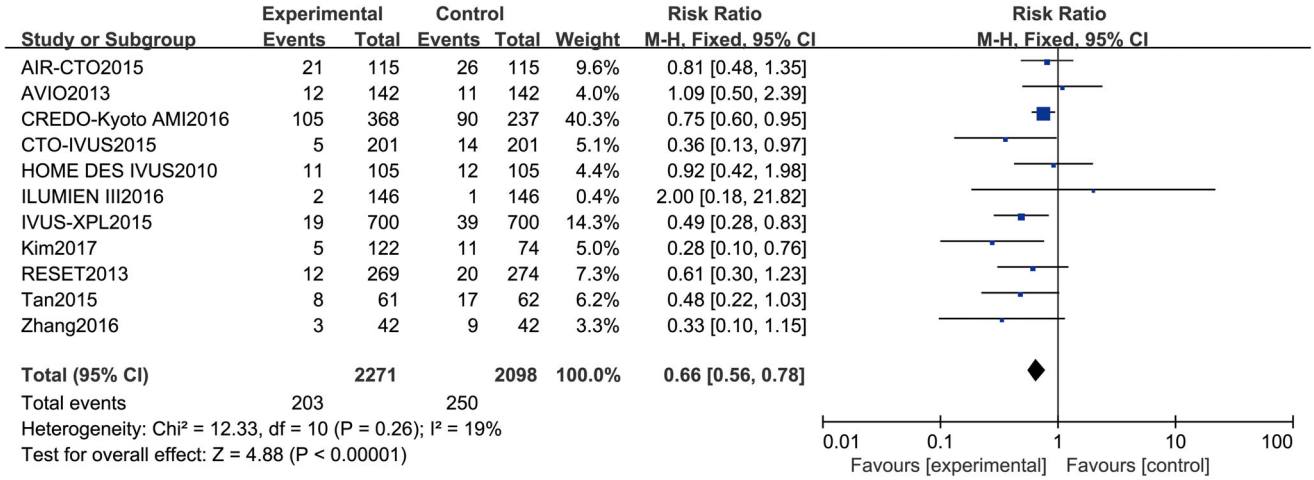

FIGURE 4 Comparison of major adverse cardiac events between intravascular ultrasound-guided group and angiography-guided group. CI, confidence interval

the data. As displayed in Figure 5, the pooled estimates of effect sizes showed significant statistical difference of cardiovascular death between the two groups (RR = 0.49, 95% CI [0.29, 0.83], $P = 0.007$).

4.1.3 | Myocardial infarction

Twelve studies[10–21] reported MI including a total of 6399 patients (3415 in the angiography-guided PCI group and 2984 in the IVUS-guided PCI group). There was no statistical between-study heterogeneity in the RR of studies ($P = 0.61$, $I^2 = 0\%$); therefore, the fixed-effects model was used for pooling the data. As displayed in Figure 6, the pooled estimates of effect sizes showed no significant statistical difference in progression-free survival between the two groups (RR = 0.76, 95% CI [0.59, 0.99], $P = 0.05$).

4.1.4 | Target lesion revascularisation

Ten studies[10,11,13–20] reported TLR, including a total of 4784 patients (2542 in the angiography-guided PCI group and 2242 in the IVUS-guided PCI group). There was no statistical between-study heterogeneity in RR of studies ($P = 0.95$, $I^2 = 0\%$); therefore, the fixed-effects model was used for pooling the data. As displayed in Figure 7, the pooled estimates of effect sizes showed significant statistical difference in TLR between the two groups (RR = 0.72, 95% CI [0.57, 0.91], $P = 0.006$).

4.1.5 | Stent thrombosis

Eight studies[10–17,19,20] reported stent thrombosis, including a total of 5573 patients (2960 in the angiography-guided PCI group and 2613 in the IVUS-guided PCI group). There was no statistical between-study heterogeneity in the RR of studies ($P = 0.61$, $I^2 = 0\%$); therefore, the fixed-effects model was used for merging. As displayed in Figure 8, the pooled estimates of effect sizes showed no significant statistical difference in stent thrombosis between the two groups (RR = 0.82, 95% CI [0.49, 1.37], $P = 0.44$).

4.1.6 | All-cause death

Three studies[17,19,20] reported all-cause death, including a total of 2734 patients (2960 in the angiography-guided PCI group and 2613 in the IVUS-guided PCI group). There was

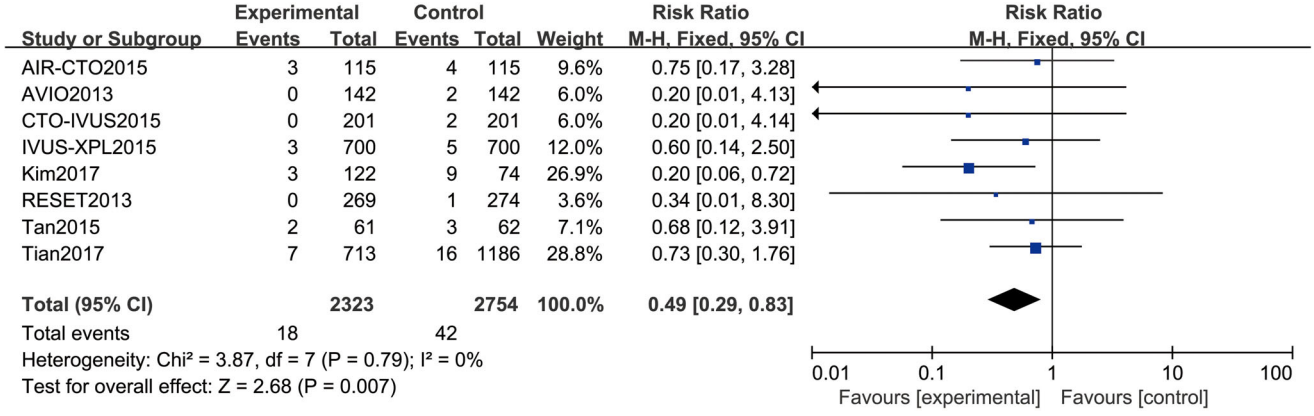

FIGURE 5 Comparison of cardiovascular death between intravascular ultrasound-guided group and angiography-guided group. CI, confidence interval

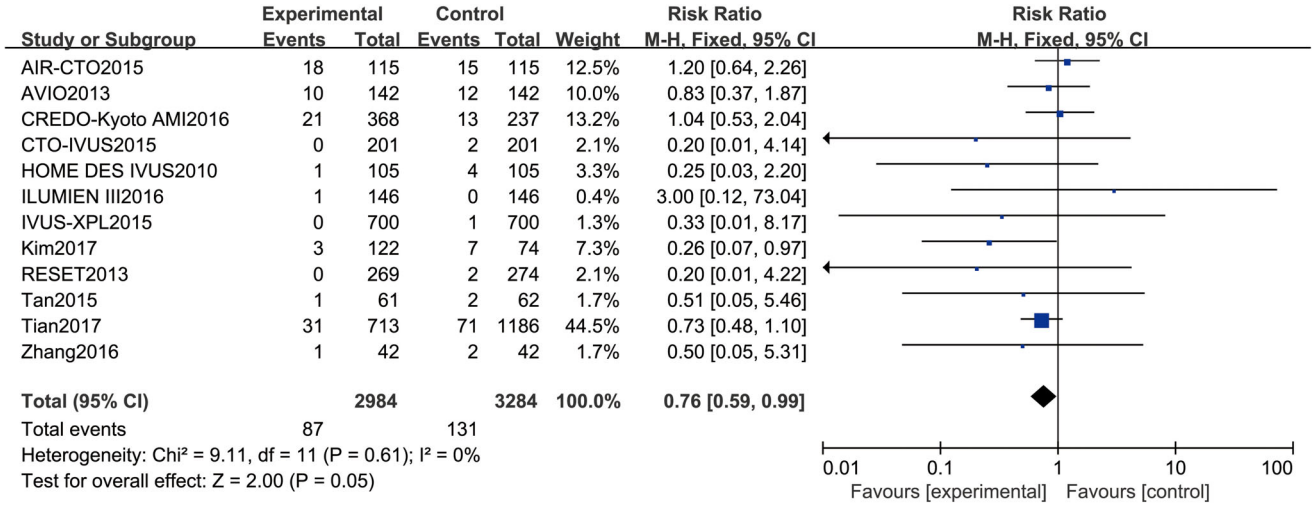

FIGURE 6 Comparison of myocardial infarction between intravascular ultrasound-guided group and angiography-guided group. CI, confidence interval

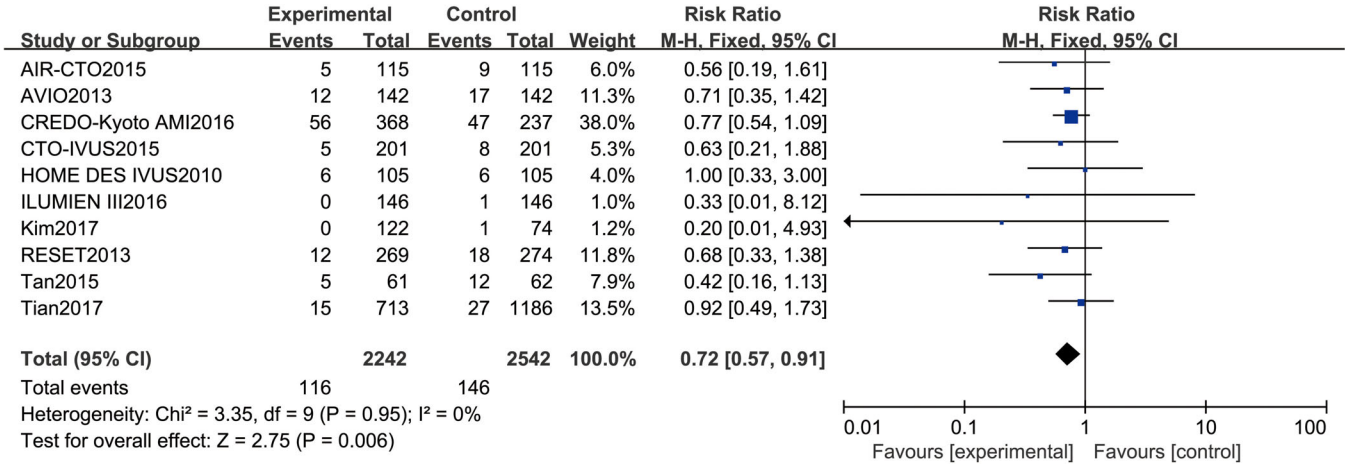

FIGURE 7 Comparison of target lesion revascularisation between intravascular ultrasound-guided group and angiography-guided group. CI, confidence interval

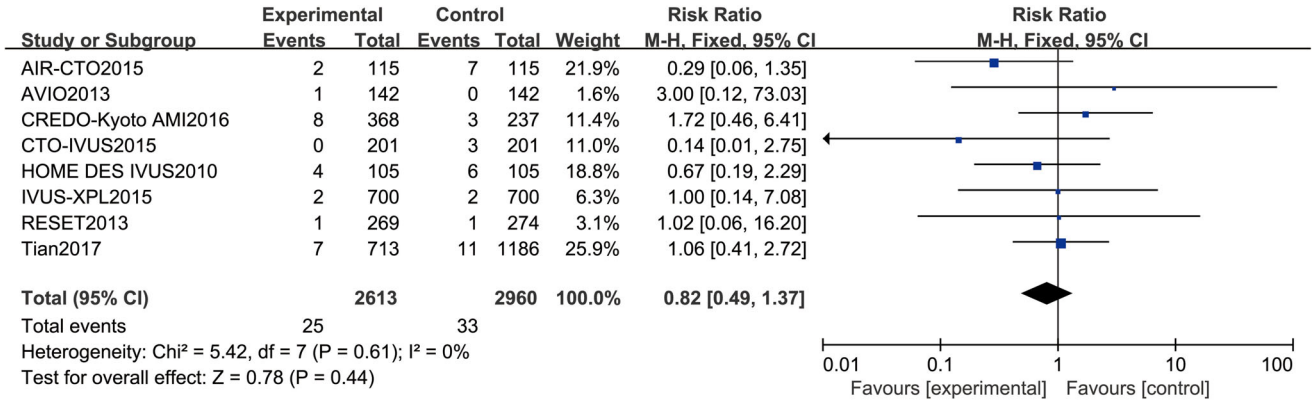

FIGURE 8 Comparison of stent thrombosis between intravascular ultrasound-guided group and angiography-guided group. CI, confidence interval

no statistical between-study heterogeneity in RR of studies ($P = 0.81$, $I^2 = 0\%$); therefore, we used the fixed-effects model for pooling the data. As displayed in Figure 9, the pooled estimates of effect sizes showed significant statistical difference in all-cause death between the two groups (RR = 0.72, 95% CI [0.51, 1.01], $P = 0.05$).

4.1.7 | Trial sequential analysis

The evaluation of MACEs through TSA indicated that the cumulative Z curve crossed the trial sequential monitoring boundaries for superiority, but there was no sufficient information on size. It further confirmed a definite decrease in MACEs through IVUS guidance, as displayed in Figure 10.

FIGURE 9 Comparison of all-cause death between intravascular ultrasound-guided group and angiography-guided group. CI, confidence interval

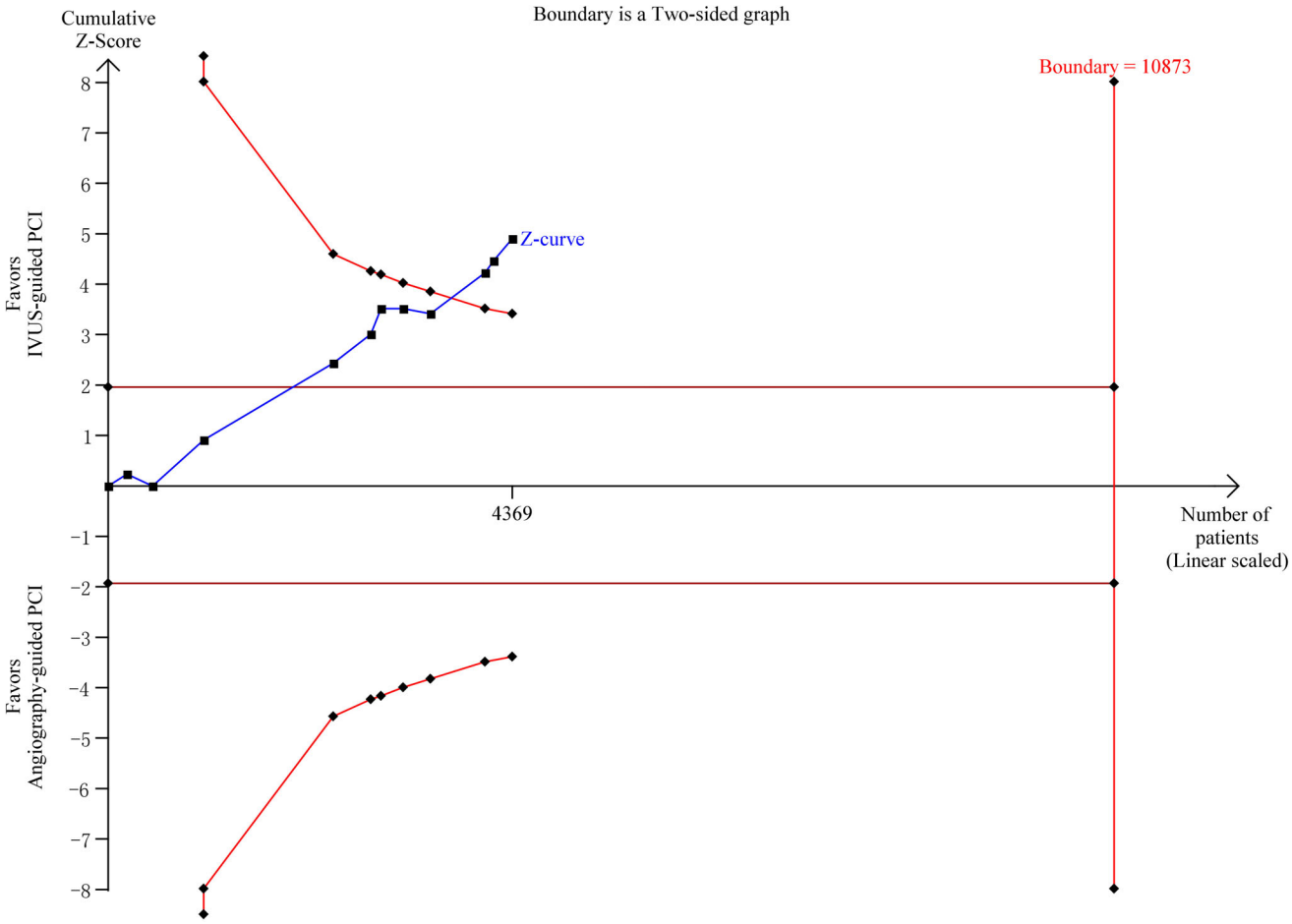

FIGURE 10 Trial sequential analyses for major adverse cardiac events. IVUS, intravascular ultrasound; PCI, percutaneous coronary intervention

5 | DISCUSSION

Coronary atherosclerotic heart disease is a cardiovascular disease with a rapid increase in both morbidity and mortality, and early diagnosis and proper evaluation of the severity of coronary lesions will help develop effective treatment options. Coronary angiography has been considered a "gold standard" to evaluate the severity of coronary artery lesions and to diagnose coronary heart disease. However, with the application of IVUS, the degree of critical lesions is evaluated along with the identification of vulnerable plaque, calcification lesions, interlayer, and wall hematoma, and traditional coronary angiography significantly lags behind IVUS, especially in some complex lesions conditions, such as bifurcation lesions, left main lesion, chronic complete occlusion, small vascular lesions, stents within restenosis, and other lesions.[22]

Our present pooled analysis of 12 RCTs demonstrated that the IVUS-guided group had significantly improved clinical outcomes, including MACEs, cardiovascular death, all-cause death, MI, and TLR. However, its effect on stent thrombosis was not statistically significantly different from the angiography-guided DES implantation group. Guagliumi et al[23] showed that hypertension, diabetes, and smoking have a different effect between late stent thrombosis and very late stent thrombosis, which may be related to delayed

endometrial coverage and incomplete healing. There is a remarkable difference between the IVUS-guided and angiography-guided group on baseline characteristics such as current smoker ratio in our study. Therefore, IVUS-guided DES implantation is superior to coronary angiography-guided DES implantation in terms of stent thrombosis. However, more high-quality research should be performed to confirm the beneficial effect.

The value of IVUS-guided DES in the treatment of coronary heart disease remains controversial. The AVIO study[11] found that IVUS was superior to coronary angiography in the guidance of DES treatment, with its effect of increasing the minimum lumen diameter and reducing the incidence of stent adherent, but it cannot effectively improve the patient's clinical outcome, especially in patients with simple lesions. Yoon et al[24] also pointed out that IVUS had a better effect than coronary angiography in the treatment of DES lesions; even in patients with diabetes as a high-risk factor or acute coronary syndrome, its clinical benefit is not obvious. The findings from the CREDO-Kyoto AMI trial[17] also suggested that IVUS guidelines had no effect on reducing the incidence of TVR and TLR in first-episode stent thrombosis-segment elevation MI. However, most of the studies that conducted IVUS-guided DES predicted the clinical outcomes of coronary heart disease, and the limited sample size in the above study and the potential differences between baseline and lesion characteristics of patients may affect the reliability of the results. The CREDO-Kyoto AMI study mixed implants with a large number of bare metal stents, so the conclusions of this study cannot be fully extended to IVUS-guided DES treatment.

A recent meta-analysis of relevant topics showed that, in the treatment of coronary heart disease DES, IVUS-guided DES implantation can provide a beneficial effect in clinical outcomes in comparison with angiography-guided DES implantation.[25–31] Shin et al[30] reported a meta-analysis with data on individual patient levels from 2345 randomised patients. A new generation of IVUS-guided DES implantation can significantly reduce stent thrombosis, the risks of cardiac death, or MI for complex lesions. Three RCTs were performed particularly for left main lesions.[16,18,20] Tan et al[18] demonstrated that the IVUS-guided group had a lower composite of non-fatal MI, death, or TLR (13.1% vs 29.3%, $P = 0.031$). Tian et al[20] reported MI and all-cause death at 3 years between IVUS vs angiography guidance. IVUS guidance provided a significantly lower incidence of the composite of MI and all-cause death (hazard ratio = 0.82, 95% CI [0.49, 1.37]; $P = 0.001$). Moreover, a recent pooled analysis[32] has suggested that IVUS-guided PCI is superior to angiography-guided PCI in the left main coronary artery disease based on risk reduction in both all-cause and cardiac death. Two RCTs[15,19] were performed particularly for chronic total occlusion. In the AIR-CTO trial[19], earlier lumen loss was observed in the IVUS-guided group compared with the angiography-guided group (0.28 vs 0.46 mm, $P = 0.025$). In the second RCT,[15] the post-procedural minimal lumen diameter was significantly larger in the IVUS-guided group (2.64 vs 2.56 mm, $P = 0.025$). In patients with long lesions, IVUS-guided implantation provided a remarkably lower rate of MACEs at 1 year compared with angiography-guided implantation.[12,14] Therefore, it is noteworthy that IVUS guidance is beneficial for patients with complex lesions.

Several limitations of the current analysis should be discussed. First, the included studies in the pooled analysis are different in study design, patient baseline characteristics, study endpoints, and definitions. Second, the use of different types of DES in each study failed to distinguish the clinical outcomes of angiography-guided implantation or IVUS-guided implantation in terms of the treatment of coronary heart disease with different types of DES. Third, clinical beneficial outcomes of IVUS-guided implantation at different baseline levels and type of lesions were not further compared. The relevant research needs to be further improved from the following aspects: larger sample size; right random allocation and allocation of hidden programs; sufficient follow-up duration to observe the short-term and long-term effects; and stratified analysis of lesion characteristics, different types of DES, and patient baseline characteristics as independent factors. More comprehensive evaluation of the efficacy of IVUS-guided implantation should be undertaken in the future.

6 | CONCLUSIONS

In summary, IVUS-guided DES implantation appears to have significantly improved clinical outcomes compared with angiography-guided DES implantation, including MACEs, cardiovascular death, all-cause death, TLR, and MI. However, its effect on stent thrombosis requires further confirmation. More high-quality RCTs are warranted to verify the findings and conclusions of the current meta-analysis and determine the IVUS-guidance effect on different patients with lesions.

CONFLICTS OF INTEREST

The authors have no conflicts of interest to report.

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