

Comparison of clinical outcomes between intravascular optical coherence tomographyguided and angiography-guided stent implantation A meta-analysis of randomized control trials and systematic review

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Abstract

Objective: This systematic review was designed to evaluate the overall efficacy of optical coherence tomography (OCT)-guided implantation versus angiography-guided for percutaneous coronary intervention.

Methods: The following electronic databases, such as CENTRAL, PubMed, Cochrane, and EMBASE were searched for systematic reviews to investigate OCT-guided and angiography-guided implantation. We measured the following 7 parameters in each patient: stent thrombosis, cardiovascular death, myocardial infarction, major adverse cardiac events (MACE), target lesion revascularization (TLR), target vessel revascularization (TVR), all-cause death.

Results: In all, 11 studies (6 RCTs and 5 observational studies) involving 4026 subjects were included, with 1903 receiving intravascular ultrasound-guided drug-eluting stent (DES) implantation and 2123 using angiography-guided DES implantation. With regard to MACE, MT, TLR, TVR, stent thrombosis and all-cause death, the group of OCT-guided implantation had no significant statistical association with remarkably improved clinical outcomes. However, its effect on cardiovascular death has a significant statistical difference in angiography-guided implantation group.

Conclusion: In the present pool analysis, OCT-guided DES implantation showed a tendency toward improved clinical outcomes compared to angiography-guided implantation. More eligible randomized clinical trials are warranted to verify the findings and to determine the beneficial effect of OCT-guidance for patients.

Abbreviations: MACE = major adverse cardiac events, MI = myocardial infarction, OCT = optical coherence tomography, PCI = percutaneous coronary intervention, TLR = target lesion revascularization, TSA = trial sequential analysis, TVR = target vessel revascularization.

Keywords: angiography, meta-analysis, optical coherence tomography, percutaneous coronary intervention

1. Introduction

Angiography guided percutaneous coronary intervention (PCI) has been a standard imaging modality since 1970s. However, in the presence of the limitations of the existing imaging techniques such as image noise, intensity inhomogeneity, and so on, the complexity of the cardiac dynamics and the lack of unambiguous reference landmarks within the myocardium, it remains challenging to robustly and reliably solve these problems.^[1] Intravascular ultrasound (IVUS) improves the accuracy of the assessment of vessel overlap, shortening, and calcification while providing more detailed information on plaque burden, morphology, and calcification distribution.^[2] Optical coherence tomography (OCT) is an emerging intracoronary imaging technique following IVUS.

Compared with IVUS, OCT has a very high resolution, and it has attracted attention in the evaluation of vulnerable plaques and guided stent placement, especially in the field of coronary heart disease diagnosis and treatment such as acute coronary syndrome.^[2] In the European Society of Cardiology (ESC) 2013 Guidelines for the Management of Stable Heart Disease, OCT's assessment of lesion characteristics and optimization of stent placement were Type IIb recommendations (Level of evidence B).^[3] The overall level of evidence was equivalent to IVUS. In the 2014 ESC/European Cardiothoracic Surgery Association Guidelines for Cardiovascular Revascularization, OCT's recommendation for optimizing PCI was upgraded to IVUS-equivalent Class IIa.^[4] The ILUMIEN I study published in 2015 showed that preoperative and/or postoperative OCT of PCI can affect the interventional strategy of the surgeon.^[5] Recent ILUMIEN II study has shown that OCT is not inferior to IVUS in guiding stent expansion.^[6]

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OCT is the highest resolution intraluminal imaging technology at present and able to be more accurately detect subtle stent morphologies with a resolution 10 times that of IVUS.^[7] However, recently, the evidence demonstrating the clinical usefulness of OCT are inadequate for sufficiently powered randomized clinical trials. We, therefore, performed a systematic review and meta-analysis of all available trials to investigate the efficacy and safety routine OCT-guided PCI.

2. Materials and methods

2.1. Ethical approval

Ethics approval was waived because this study does not involve any human participants or animals.

2.2. 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 March 2018, based on the MeSH terms and free keywords: "percutaneous coronary intervention; " "OCT;" "optical coherence tomography; " "optical frequency domain; " "OFDI." All relevant publications were identified without language restrictions; in which we identified full-text papers from reference materials for further evaluation.

2.3. Inclusion criteria

Articles that were related to the following inclusion criteria were included in this analysis:

- patients underwent PCI using a metallic drug-eluting stent (DES);
- (2) trails focused on comparing OCT-guided implantation and angiography-guided or IVUS-guided implantation;
- (3) more than 1 of the following parameters were mentioned in studies: stent thrombosis, cardiovascular death, myocardial infarction (MI), major adverse cardiac events (MACE), target lesion revascularization (TLR), target vessel revascularization (TVR), all-cause death;
- (4) randomized controlled trials (RCTs), observational studies.

Studies should be excluded with the following exclusion criteria:

- (1) trials without control group;
- (2) the repoted data was clearly erroneous or incomplete, and were unable to provide research outcomes;
- (3) duplicated previous publications.

2.4. Risk-of-bias assessments

The risk of bias was evaluated in each mentioned studies 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."

2.5. Data selection and extraction

After screening process, studies were then assigned to certain topic (s). Using Thomson Research Software (EndNote X4), we extracted relevant data for accuracy assessment. Any unclear information should be with more details of original articles. "excluded (reason)," "pending," and "included" were involved into the "notes" column. We should retract "pending" articles from the references.

A self-designed data extraction form was used to independently extract contents by 2 researchers including lead author, year of publication, study design, participant characteristics, outcomes measures, and follow-up time. The literature screening process, data extraction, and quality evaluation process were performed separately by 2 reviewers. In case of disagreement, a third investigator would be involved to help resolve the disagreement through discussion.

2.6. Statistical analysis

The Cochrane Collaborations have offered Review Manager Software (RevMan5.3) for statistical analysis. Odds ratios (OR) and its 95% confidence interval (CI) were utilized for binary data and effect size in the meta-analysis. The chi-square was used to assess the significance of heterogeneity, and the degree of heterogeneity was then examined through the I^2 statistic. Fixed-effect model was used if the assessment of heterogeneity was insignificant ($P > .1, I^2 \le 50\%$). If the source of heterogeneity was uncertain, we used the random-effect model for further analysis.

2.7. 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 was consisted of type power = 80%, I error α = 5%, as well as 2-sided testing. Hypothesis was that 25% and 50% relative reduction could be obtained through OCT guidance in the risk of MACE and stent thrombosis, and in the angiography-guided group, there was 10% anticipated event rate for MACE and 1.5% for stent thrombosis. 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 of 735 articles were retrieved. After 76 duplicates were deleted from the total amount of articles, 626 irrelevant citations were excluded based on the review of titles and abstracts. Intensive reading full-text review of the 33 included articles, 22 articles were further eliminated. Finally, a total of 11 studies^{110–20]} published between 2015 and 2018 were assessed for eligibility in the meta-analysis (Fig. 1).

3.2. Quality assessment

There were 5^[10,14,16–18] studies reference to random sequence generation used web-based system or random table, while 1 study^[11] was just reported as randomized trials and without randomization description; 5 studies^[12,13,15,19,20] of random



grouping method were assessed as a high risk of bias. 4 trials^[10,11,14,17] described allocate patients by sealed opaque envelopes. Because the nature of interventions, it was not possible to blind the operator, investigator, or patient for the allocated implantation technique in all trails, but the operator was blinded to the postprocedure OCT images in 1 trail.^[11] Most trials had comparable baselines clinical characteristics except that 1 trail^[17] was statistically significant difference when comparing the 2 groups for hypertension. Blinding of outcome assessment was independent in most studies except to 2 trails.^[12,13] None of the included studies had a selective report nor incomplete report. In all, 3 studies^[10,11,14] were with high methodological quality, 3 studies with moderate quality^[16–18] and the rest 5 studies with low quality.^[12,13,15,19,20]Figure 2 and Figure 3 presented a summary of the quality assessment process.

3.3. Characteristics of study selection

Totally, 4026 selective patients were included in this metaanalysis, 1903 receiving OCT-guided DES implantation, 2123 using angiography-guided DES implantation. Studies included patients with coronary heart disease, acute coronary syndromes, non-ST-segment elevation myocardial infarction, or ST-segment elevation myocardial infarction. Among those patients, follow-up period varied from 30 days to 12 months, sample sizes from 69 to 817, and mean ages from 50 to 80 years. No significant statistical difference was observed when comparing the 2 groups for baseline clinical characteristics such as diabetes and smoker. Hypertension was found significant statistical difference in 1 trail.^[17] Intervention strategies were similar among most of the trials. The major characteristics of included studies are depicted in Table 1.

4. Outcomes and synthesis of results

4.1. MACE

Eight studies^[10–16,18] reported MACE, included a total of 2413 patients (1197 in OCT-guided PCI group and 1216 in angiography-guided PCI group). There was no statistical



Figure 2. Quality assessment summary for included studies.

between-study heterogeneity in OR of studies (P = .46, $l^2 = 0\%$), we used a fixed effect model for merging. As displayed in Figure 4, pooled estimates of effect sizes showed no significant statistical difference of MACE when comparing the 2 groups (OR = 0.72, 95% CI [0.50, 1.03], P = .07).

4.2. Stent thrombosis

Nine studies^[10,11,13,15-20] reported stent thrombosis, included a total of 3682 patients (1724 in OCT-guided PCI group and 1958 in angiography-guided PCI group). There was no statistical between-study heterogeneity in OR of studies (P=.52, $I^2=0\%$), a fixed effect model was used for merging. As displayed in Figure 5, pooled estimates of effect sizes showed no significant statistical difference of stent thrombosis when comparing 2 groups (OR=0.53, 95% CI [0.25, 1.12], P=.09).

4.3. MI

Nine studies^[10,13–20] reported MI including a total of 3798 patients (1789 in OCT-guided PCI group and 2009 in angiography-guided PCI group). There was no statistical between-study heterogeneity in OR of studies (P=.83, I^2 = 0%), a fixed effect model was used for merging. As displayed in Figure 6, pooled estimates of effect sizes showed no significant statistical difference of MI when comparing 2 groups (OR = 0.80, 95% CI [0.55, 1.18], P=.26).

4.4. TLR and TVR

Five studies^[10,13–15,18] reported TLR, included a total of 1432 patients (709 in OCT-guided PCI group and 723 in angiography-guided PCI group). Six studies^[13,16–20] reported TVR, included a total of 3009 patients (1404 in OCT-guided PCI group and 1605 in angiography-guided PCI group). There was no statistical between-study heterogeneity in OR of studies (TLR: P = .16, $I^2 = 40\%$; TVR: P = .31, $I^2 = 17\%$), fixed effect model was used for merging. As displayed in Figure 7, pooled estimates of effect sizes showed no significant statistical difference of TLR, TVR when

comparing 2 groups (TLR: OR=0.49, 95% CI [0.21, 1.11], P=.09; TVR: OR=0.71, 95% CI [0.44, 1.13], P=.15).

4.5. All-cause death and cardiovascular death

Five studies^[10,13,14,17,19] reported all-cause death, cardiovascular death, included a total of 1949 patients (988 in OCT-guided PCI group and 961 in angiography-guided PCI group). Six studies^[11,15,16,18–20] reported cardiovascular death, included a total of 2604 patients (1176 in OCT-guided PCI group and 1428 in angiography-guided PCI group). We utilized a fixed effect model for merging. As displayed in Figure 8, pooled estimates of effect sizes showed no significant statistical difference of all-cause death (OR=0.59, 95% CI [0.33, 1.04], P=.07), significant statistical difference of 2 groups (OR=0.38, 95% CI [0.19, 0.74], P=.005).

4.6. Sensitivity analysis

By omitting 1 study at a time, the sensitivity analysis was conducted (Table 2). With regarding to MACE, the pooled results altered obviously when omitting the study of Ali et al^[10] or Kala et al^[14] Notably, significantly improved result was found after omitting these 2 studies. On the other hand, for stent thrombosis, the pooled result altered remarkably in the absence of the study of Sheth et al,^[20] significantly improved result was found after omitting this study.

4.7. TSA

The evaluation of MACE though TSA indicated that the cumulative Z curve did not cross the trial sequential monitoring boundaries for superiority, and only 18.8% (1504 patients) of required information size (7983 patients) was accrued. For the assessment of stent thrombosis, only 21.0% (1303 patients) of required information size (6209 patients) was accrued. The Z curve did not cross any monitoring boundaries. The TSA results indicate that inadequate power for making a clear conclusion upon MACE and stent thrombosis these 2 endpoints. As displayed in Figures 9 and 10.





5. Discussion

Our meta-analysis of 6 RCTs and 5 observational studies comprising a total of 4026 patients, showed that OCT-guided DES implantation was not significantly associated with a lower incidence of MACE, MT, TLR, TVR, stent thrombosis and allcause death, while only significantly associated with a lower incidence of cardiovascular death. In present pool analysis, OCTguided DES implantation showed a tendency toward improved clinical outcomes compared to angiography-guided implantation.

The preoperative PCI OCT test can accurately assess pretreated lesions and help the surgeon select the appropriate stent and the location of the stent release. At the same time, OCT can provide the lumen and diameter of the reference vessel, which would be an excellent parameter with potential to be evaluated in future studies for the surgeon to determine prognostic implications.^[21] According to the size of the reference blood vessel, a safe postdilation balloon is selected to prevent insufflation.^[22] In addition, OCT imaging before PCI can evaluate plaque morphology and predict the outcome after PCI. The OCT test after PCI can accurately evaluate stent expansion, stent adherence, stent prolapse, stent edge dissection, and stent thrombosis, providing surgeons with more anatomical information and helping surgeons optimize PCI strategy.^[23] Stent failure is an important factor in the long-term prognosis of patients after PCI. OCT can accurately assess the cause of stent failure. Therefore, OCT is recommended for follow-up after PCI.

The new generation of FD-OCT can quickly and safely scan the left main lesion (except coronary artery lesions), determine the lesion type, evaluate the size of the lumen, and the malapposition, edge dissection, and tissue prolapse after stent placement, obviously better than angiography-guided implantation and IVUS.^[24] However, it is worth noting that due to the limited depth of OCT scan, OCT is not recommended for routine use in left main lesions. Bifurcation lesions are one of the complex lesions with high failure rate of coronary artery dissection. Preoperative OCT examination can accurately measure the degree of stenosis, length of lesions, plaque distribution, and nature of the main branch and branch opening, which helps the surgeon to choose the right one interventional device and branch stent treatment strategy.^[25,26] The real-time 3D imaging capabilities of the new generation of OCT systems can also provide the spatial distribution and structure of blood vessels, especially for the display of bifurcation openings.^[27] Studies have shown that 3D-OCT guidance for bifurcation stent placement is feasible and can reduce stent malapposition.^[28] Therefore, OCT can be considered when clinically guiding treatment of bifurcation lesions.

Pathological control studies have shown that the sensitivity (95-96%) and specificity (97%) of the calcification lesions detected by OCT are high. Accurate detection of preoperative calcified lesions is critical for the choice of revascularization. OCT imaging technology has obvious advantages in the field of absorbable stents. The current average thickness of bioresorbable stents is relatively large (114-228 µm), and compared with metal stents, bioresorbable materials are harder and less malleable.^[29] Absorbable stents are well-prepared to respond to lesions and are accurate. Vascular diameter and lesion characteristics are measured to select the appropriate size of the absorbable stent.^[30] Therefore, compared with angiographyguided implantation, OCT is an extremely necessary influencing tool for the selection of the correct size of the stent and the process of guiding PCI. In addition, In addition, OCT has unique advantages for the follow-up evaluation of bioresorbable stents.

Our meta-analysis showed that OCT-guided PCI may be numerically reduced cardiac death compare to angiographyguided PCI, while statistical significance was not attained for MACE and the remaining 5 outcomes. Sensitivity analysis found that the pooled estimate of MACE altered obviously after excluding the ILUMIEN III study^[10] (OR 0.60, 95% CI 0.45–0.80, P=.005)and the study of Kala et al^[14] (OR 0.60, 95% CI 0.45–0.80, P=.005). Similarly, the pooled estimate of stent thrombosis altered remarkably in the absence of the study of Sheth et al (OR 0.60, 95% CI 0.45–0.80, P=.005). A

Table 1 Characteris	tics of included stu	udies.								
				Patients	baseline charac	teristics				
Author, yr	Study design	Procedures	Gender M/F	Mean age	Diabetes (%)	Hypertension (%)	Smoker (%)	Treated lesion	Outcome measures	Follow-up
Ali, 2016	RCT/multicenter	OCT	109/49	66 (59–72)	33%	78%	18%	Coronary heart disease	(1)2)3(4)7	30 d
		Angiography	107/39	67 (56–74)	29%	75%	24%))))	
Antonsen, 2015	RCT/single centre	OCT	36/14	61.8 (9.4)	16%	56%	46%	NSTEMI	(126)	6 mo
) - -		Angiography	34/16	62.6 (11.0)	10%	56%	36%			
Hamshere, 2018	Observational/ single centre	OCT	29/14	56.3 (9.5)	32.6%	48.8%	46.5%	Coronary artery disease		3 mo
2		Angiography	29/7	56.4 (11.5)	36.1%	69.4%	44.4%			
lannaccone,	Observational/	OCT	226/44	60 (13)	17%	49%	57%	Acute coronary	123457	700 d
0107		Andiodraphy	507/43	61 (12)	18%	70 Z V	58%			
Kala, 2018	RCT/multicenter	OCT OCT	83/22	57 (46-70)	17%	50%		STEMI	(1)(3)(4)(7)	9 mo
		Angiography	87/9	59 (47–72)	26%	52%	59%))))	
Kim, 2016	Observational/ single_centre	OCT	92/30	61.2 (10.4)	28.7%	46.7%	66.4%	Coronary artery disease	12346	12 mo
		Angiography	122/46	63.0 (10.3)	38.1%	46.4%	59.5%			
Kubo, 2017	RCT/multicenter	OCT	315/97	(6) (6)	41.0%	76.5%	16.3%	Coronary artery disease	(1)2(3)5(6)	12 mo
		Angiography	322/83	68 (9)	40.7%	73.8%	18.0%)))	
Meneveau, 2016	RCT/multicenter	OCT	95/25	60.8 (11.5)	21.7%	55.8%	39.2%	NSTE-ACS	2357	6 mo
		Angiography	91/29	60.2 (11.3)	15.8%	41.7%	42.5%			
Otake, 2018	RCT/multicenter	OCT	43/11	68 (8)	77.8%	37%	16.7%	Coronary artery disease	(123456)	12 mo
		Angiography	41/8	68 (9)	73.5%	46.9%	20.4%			
Prati, 2012	Observational/ multicenter	OCT	282/73	64.8 (11.5)	75.5%	24.2%	34.3%	Coronary artery disease	23567	12 mo
		Angiography	273/82	67.0 (11.5)	73.8%	29.0%	33.7%			
Sheth, 2016	Observational/ multicenter	OCT	167/47	60.9 (11.5)	NR	17.8%	43.5%	STEM	2356	12 mo
		Angiography	354/74	61.2 (12.1)	NR	18.5%	43.0%			
NR = not report, Outcome measur	NSTE-ACS = non-ST-segmer es: (1) major adverse card.	int elevation acute coro liac events; (2) stent	nary syndromes, N thrombosis; (3) n	STEMI = non–ST-segmen nyocardial infarction; ④	t elevation myocardi) target lesion revas	al infarction, STEMI = ST cularization; (5) target	-segment elevation vessel revasculariz	myocardial infarction. $(\overline{\mathbb{C}})$ cardiovascular death; $(\overline{\mathbb{C}})$) all-cause death.	

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	Experim	ental	Contr	lo		Odds Ratio		Odd	Is Ratio	
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% C		M-H, Fi	xed, 95% Cl	
Ali2016	4	158	1	140	1.4%	3.61 [0.40, 32.69]		<u> </u>		-
Antonsen2015	0	40	2	45	3.3%	0.21 [0.01, 4.61]	-			
Hamshere2018	2	36	7	43	8.4%	0.30 [0.06, 1.56]				
lannaccone2016	31	270	41	270	50.9%	0.72 [0.44, 1.19]		-	+	
Kala2018	3	105	1	96	1.4%	2.79 [0.29, 27.33]		3	· · · · · · · · · · · · · · · · · · ·	
Kim2016	4	122	9	168	10.3%	0.60 [0.18, 1.99]				
Kubo2017	12	412	14	405	19.2%	0.84 [0.38, 1.83]		3	•	
Otake2018	0	54	3	49	5.1%	0.12 [0.01, 2.42]	+			
Total (95% CI)		1197		1216	100.0%	0.72 [0.50, 1.03]				
Total events	56		78			8 8 8				
Heterogeneity: Chi ² =	(P=0.4	46); $l^2 = 0$	1%			-			400	
Test for overall effect:	Z = 1.79 (F	P = 0.07)					0.01 Favo	urs [experimental	1 10] Favours [control]	100

Figure 4. Comparison of major adverse cardiac events between OCT-guided group and angiography-guied group. OCT = optical coherence tomography.



Figure 5. Comparison of stent thrombosis between OCT-guided group and angiography-guied group. OCT = optical coherence tomography.

	Experime	ental	Contr	ol		Odds Ratio		Odd	s Ratio	
Study or Subgroup	Events	Total	Events	Total	Weight	M-H. Fixed. 95% C		M-H, Fix	ced. 95% Cl	
Ali2016	2	158	0	140	0.9%	4.49 [0.21, 94.30]				
lannaccone2016	18	270	17	270	26.8%	1.06 [0.54, 2.11]		-	•	
Kala2018	1	105	0	96	0.9%	2.77 [0.11, 68.82]		3	1	_
Kim2016	0	122	2	168	3.5%	0.27 [0.01, 5.71]				
Kubo2017	2	412	3	405	5.1%	0.65 [0.11, 3.93]				
Meneveau2016	1	120	1	120	1.7%	1.00 [0.06, 16.17]		2	-	
Otake2018	0	54	1	49	2.6%	0.30 [0.01, 7.45]				
Prati2012	18	335	29	335	46.4%	0.60 [0.33, 1.10]			+	
Sheth2016	5	213	11	426	12.1%	0.91 [0.31, 2.64]			• • • • • • • • • • • • • • • • • • •	
Total (95% CI)		1789		2009	100.0%	0.80 [0.55, 1.18]				
Total events	47		64						100	
Heterogeneity: Chi ² =	(P = 0.8)	83); l ² = 0	1%				1		100	
Test for overall effect:	Z = 1.12 (P	= 0.26)	5				0.01 Favo	U.1 urs [experimental]	Favours [control]	100

Figure 6. Comparison of myocardial infarction between OCT-guided group and angiography-guided group. OCT = optical coherence tomography.

	Experim	ental	Contr	lo		Odds Ratio	Odds Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H. Fixed, 95% Cl	M-H, Fixed, 95% Cl
1.1 TLR							
Ali2016	3	158	1	140	1.7%	2.69 [0.28, 26.16]	
lannaccone2016	1	270	9	270	14.9%	0.11 [0.01, 0.86]	
Kala2018	2	105	1	96	1.7%	1.84 [0.16, 20.67]	
Kim2016	2	122	3	168	4.1%	0.92 [0.15, 5.57]	
Otake2018	0	54	3	49	6.1%	0.12 [0.01, 2.42]	· · · ·
Subtotal (95% CI)		709		723	28.6%	0.49 [0.21, 1.11]	-
Total events	8		17				
Heterogeneity: Chi ² =	6.66, df = 4	(P = 0.	16); $l^2 = 4$	0%			
Test for overall effect:	Z = 1.70 (P	= 0.09					
1.2 TVR							
lannaccone2016	1	270	10	270	16.6%	0.10 [0.01, 0.76]	
Kubo2017	2	412	3	405	5.0%	0.65 [0.11, 3.93]	
Meneveau2016	2	120	1	120	1.6%	2.02 [0.18, 22.54]	
Otake2018	1	54	3	49	5.1%	0.29 [0.03, 2.88]	
Prati2012	11	335	11	335	17.7%	1.00 [0.43, 2.34]	
Sheth2016	11	213	24	426	25.3%	0.91 [0.44, 1.90]	
Subtotal (95% CI)		1404		1605	71.4%	0.71 [0.44, 1.13]	•
Total events	28		52				
Heterogeneity: Chi ² =	5.99, df = 5	(P = 0.	31); $ ^2 = 1$	7%			
Test for overall effect:	Z = 1.45 (P	= 0.15)					
Total (95% CI)		2113		2328	100.0%	0.64 [0.43, 0.97]	•
Total events	36		69			che i [ci ici, sion]	
Heterogeneity: Chi2 =	12 91 df =	10 (P =	0 23) 12	= 23%			
Test for overall effect:	7 = 2.11 / P	= 0.03	0.20), 1	2070			0.01 0.1 1 10 100
Test for subgroup diffe	Z - Z.II (F	= 0.03	df = 1/	P=04	5) $I^2 = 00/$	6	Favours [experimental] Favours [control]

Figure 7. Comparison of target lesion revascularization and target vessel revascularization between OCT-guided group and angiography-guided group. OCT = optical coherence tomography.

	Experim	ental	Contr	ol		Odds Ratio		Odds	s Ratio	
Study or Subgroup	Events	Total	Events	Total	Weight	M-H. Fixed. 95% C		M-H, Fix	red. 95% CI	
1.1 All cause death										
Ali2016	0	158	0	140		Not estimable				
lannaccone2016	7	270	9	270	13.7%	0.77 [0.28, 2.10]			-	
Kala2018	0	105	0	96		Not estimable				
Meneveau2016	1	120	0	120	0.8%	3.03 [0.12, 75.00]				-
Prati2012	11	335	23	335	34.8%	0.46 [0.22, 0.96]			-	
Subtotal (95% CI)		988		961	49.4%	0.59 [0.33, 1.04]		-		
Total events	19		32			BOURDALI TA ONE OFFICIA AND THE				
Heterogeneity: Chi ² = '	1.71, df = 2	P = 0.4	43); $I^2 = 0$	1%						
Test for overall effect:	Z = 1.82 (F	P = 0.07))							
1.2 Cardiac death										
Antonsen2015	0	40	1	45	2.2%	0.37 [0.01, 9.25]				
Kala2018	2	122	5	168	6.5%	0.54 [0.10, 2.85]				
Kim2016	0	412	1	405	2.4%	0.33 [0.01, 8.05]	1			
Otake2018	0	54	0	49		Not estimable				
Prati2012	4	335	15	335	23.2%	0.26 [0.08, 0.79]		े ं		
Sheth2016	4	213	16	426	16.4%	0.49 [0.16, 1.49]			-	
Subtotal (95% CI)		1176		1428	50.6%	0.38 [0.19, 0.74]		•		
Total events	10		38							
Heterogeneity: Chi ² = (0.86, df = 4	(P = 0.9)	93); $I^2 = 0$	1%						
Test for overall effect:	Z = 2.82 (F	P = 0.00	5)							
Total (95% CI)		2164		2389	100.0%	0.48 [0.31, 0.74]		+		
Total events	29		70							
Heterogeneity: Chi ² = 3	3.44, df = 7	(P=0.	84); $ ^2 = 0$	1%			-			200
Test for overall effect:	Z = 3.31 (F	P = 0.000	09)	anel i			0.01	0.1	1 10	100
Test for subaroun diffe	rences Ch	$i^2 = 0.00$	a df = 1 (D - 0 2	2) 12 - 00/		Favo	ours [experimental]	Favours [control]	

Figure 8. Comparison of cardiovascular death and all cause death between OCT-guided group and angiography-guided group. OCT = optical coherence tomography.



Table 2

Results of sensitivity analysis.

	OR (95% CI), P _{he}	sterogeneity, <i>F</i> , n
Omitting study	MACE (fixed model)	stent thrombosis (fixed model)
Ali, 2016	0.68 (0.47–0.98), .60, 0%, 2238	0.47 (0.21–1.04), .49, 0%, 3410
Antonsen, 2015	0.74 (0.51-1.06), .42, 1%, 2460	0.54 (0.25–1.17), .42, 0%, 3623
Hamshere, 2018	0.76 (0.53-1.10), .48, 0%, 2459	
lannaccone, 2016	0.72 (0.43-1.20), .35, 10%, 1935	0.79 (0.35–1.82), .81, 0%, 3162
Kala, 2018	0.69 (0.48-1.00), .50, 0%, 2342	
Kim, 2016	0.74 (0.51-1.07), .36, 9%, 2296	0.55 (0.25–1.21), .45, 0%, 3417
Kubo, 2017	0.69 (0.46-1.04), .37, 8%, 1704	0.53 (0.24–1.17), .41, 2%, 2889
Meneveau, 2016		0.55 (0.25-1.12), .52, 0%, 3469
Otake, 2018	0.75 (0.52-1.08), .51, 0%, 2441	0.54 (0.25–1.18), .43, 0%, 3605
Prati, 2012		0.53 (0.24–1.17), .41, 2%, 3036
Sheth, 2016		0.53 (0.25–1.12), .52, 0%, 3709

CI=confidence interval, MACE=major adverse cardiac events, n=sample size, OR=odds ratio.

possible explanation for the divergence may be the inconsistency of the duration of follow-up time. For instance, the follow-up time of ILUMIEN III study^[10] was 30 days, it was too short to observe the expected outcomes. Noteworthy, the findings of our study should be cautiously interpreted, because the pool analysis included both randomized trials and observational studies which may entail some residual confounding. The present work enrolled 6 recent RCTs, TSA results indicate that inadequate power for making a clear conclusion upon MACE and stent thrombosis these 2 endpoints, which reflects more adequately powered randomized trials are required.

TSA is a Two-sided graph



Author contributions

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