Cardiovascular Intervention and Therapeutics (2019) 34:113–121
https://doi.org/10.1007/s12928-018-0529-6

ORIGINAL ARTICLE

Optical coherence tomography guidance in percutaneous coronary intervention: a meta-analysis of randomized controlled trials

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Received: 25 March 2018 / Accepted: 17 May 2018 / Published online: 12 June 2018

Abstract

The benefit of optical coherence tomography (OCT) guidance in percutaneous coronary intervention (PCI) is unclear. We aimed to assess the incremental value of adding OCT to coronary angiography in PCI by meta-analytic technique. We searched PubMed, EMBASE, Cochrane, Scopus and relevant references for randomized studies (inception through January 5, 2018 without language restrictions) and performed meta-analysis using random effects model. Major adverse cardiac events (MACE), all-cause mortality, myocardial infarction, target vessel revascularization, stent thrombosis, fluoroscopic time, contrast volume, and procedural side effects were the measured outcomes. Five randomized studies with a total population of 931 were analyzed. There was no difference in MACE between angiography plus OCT and angiography alone arms (2.5 vs. 2.0% OR 1.26; 95% CI 0.40–3.99; $P=0.69$; $I^2=5\%$). Two groups were not different in terms of all-cause mortality (0.2 vs. 0% OR 3.03; 95% CI 0.12–75; $P=0.5$; $I^2=$ not applicable), myocardial infarction (1 vs. 0.2% OR 2.21; 95% CI 0.39–12.49; $P=0.3$; $I^2=0\%$), target vessel revascularization (1.6 vs. 1.2% OR 1.36; 95% CI 0.4–4.4; $P=0.6$; $I^2=0\%$), and stent thrombosis (0.2 vs. 0.5% OR 0.7; 95% CI 0.11–4.51; $P=0.7$; $I^2=0\%$). OCT group had significantly higher fluoroscopic time and contrast volume. Our meta-analysis shows that the addition of OCT to angiography for PCI guidance is not associated with lower MACE, all-cause mortality, myocardial infarction, target vessel revascularization, or stent thrombosis. It is associated with longer fluoroscopic time and higher contrast volume.

Keywords PCI · Angiography · OCT · MACE · MI

Introduction

Intravascular imaging such as intravascular ultrasound (IVUS) and optical coherence tomography (OCT) has become popular in percutaneous coronary intervention (PCI) because of the limitations of coronary angiography which is routinely employed to guide decision making in patients undergoing PCI [1].

IVUS and OCT provide accurate assessment of luminal stenosis, plaque morphology, and extremely high spatial resolution; they can be of great value in optimizing PCI outcomes [2].

By achieving greater stent expansion, IVUS guidance has been associated with improved event-free survival compared with angiographic guidance alone [3, 4]. OCT has superior resolution compared with IVUS [5], but in many cases, the limited penetration depth of OCT prevents visualization of the vessel size. There is uncertainty in risk–benefit role of OCT in routine clinical practice in comparison with angiography or IVUS [6, 7].

A previous meta-analysis on the subject [8] included both randomized and non-randomized studies. Furthermore, the number of included studies was very small (2RCTs). Therefore, we sought to do a meta-analysis on the additive role of OCT to angiography-guided PCI in all available randomized studies and provide higher level of evidence.

Electronic supplementary material The online version of this article (https://doi.org/10.1007/s12928-018-0529-6) contains supplementary material, which is available to authorized users.

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Methodology

This review was constructed according to preferred reporting items for systematic reviews and meta-analysis (PRISMA) guidelines for systematic reviews and meta-analyses [9]. We searched Medline/PubMed, Embase, Scopus and the Cochrane Library for the publications. Databases were searched from inception to January 5, 2018 with keywords 'Optical coherence tomography guided percutaneous coronary intervention' OR 'OCT-guided percutaneous coronary intervention' OR 'OCT-guided PCI' AND 'Angiography-guided percutaneous coronary intervention' OR 'Angiography-guided PCI' in various combinations. Search strategy did not include the MeSH term and it was adapted for each database as necessary. In addition to the computer search, we manually reviewed the reference list of all included studies and published reviews to complete the search. Search strategy, study selection and meta-analysis were guided by a written protocol. Two investigators (SPS and KD) independently performed the database search and agreed on the final study selection.

We included studies that meet all the of the following criteria: (1) randomized studies comparing OCT-guided PCI with angiography-guided PCI and (2) a report of at least one of the outcomes of interest (major adverse cardiac events or MACE, all-cause mortality, nonfatal MI, stent thrombosis, or repeat revascularization). We excluded abstracts without full-text publications. Also excluded were abstracts from annual meeting as our protocol pre-specified inclusion of full-text articles only.

First, items for data collection and the methodology for event count extraction were standardized. Two authors (SPS and KD) extracted data from the selected studies in duplicate using a standardized data extraction table. Data were extracted on study characteristics (author, journal, year of publication, number of patient, study design, follow-up duration, inclusion/exclusion criteria, primary and secondary outcomes), patients' characteristics (age, sex, types of coronary events, DM, HTN, smoking status, etc.); outcomes of interest and adverse events. Event count for the primary and secondary outcomes was extracted as reported by the individual studies.

Our primary aim was to see if the addition of OCT to angiography in PCI lowers MACE. Our secondary endpoints were components of MACE, fluoroscopic time, contrast volume, and adverse events related to procedures.

Outcome definition

All-cause mortality Death by any cause during the study period.

MI Only two studies provided the definition of MI. ILUMIEN III [10] used consensus definition of society of cardiovascular angiography and intervention [11], while DOCTORS trial [12] used third Universal definition of MI [13].

Repeat revascularization Any revascularization procedures done after index PCI.

Stent thrombosis All the studies defined stent thrombosis as per the Academic Research Consortium Definitions criteria (ARCD) [14].

MACE All studies defined MACE as composite outcome of all-cause mortality, myocardial infarction, repeat target vessel revascularization and stent thrombosis.

Statistical analysis

The meta-analysis was performed using a random effects model with the help of review manager (RevMan 5.2, Cochrane Collaboration, Nordic Cochrane Center, Copenhagen, Denmark) for statistical analyses. Categorical variables were pooled as an odds ratio (OR) with 95% confidence interval (CI). For the continuous variable, mean difference was calculated with corresponding 95% confidence interval. The P value < 0.05 (two-tailed) was considered statistically significant. Study heterogeneity was evaluated by Cochrane's Q and I^2 index.

The quality of the included studies was assessed independently by two authors (SPS and KD) using the Cochrane Collaboration tool for assessing risk of bias. We found no evidence of significant bias (Supplementary Fig. 1). There was high risk of performance bias as blinding of participants and personnel were not uniform. Publication bias was not assessed, because the included number of studies was less than ten [15].

Results

The initial literature search identified 259 studies. A flow chart of the study identification and screening is presented in Fig. 1. A total of five studies were included in the meta-analysis [10, 12, 16–18]. There were a total of 931 patients; 467 in angiography arm and 464 in angiography plus OCT-guided arm. Average age of the patient was 60 and more than 70% comprised of male. Details on the study and patients characteristics are included in

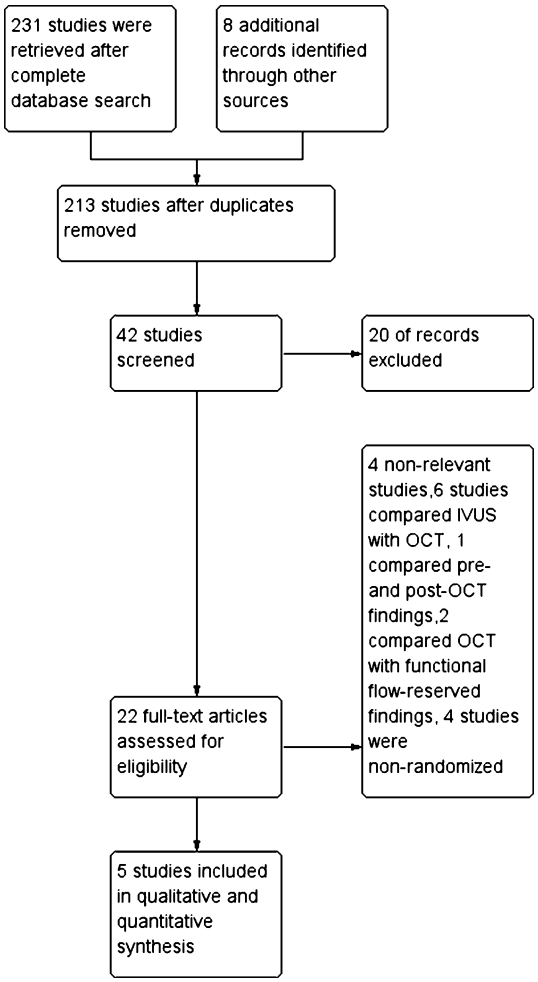

Fig. 1 Flow diagram of the study

Table 1. Details on the outcomes of interest are presented in Table 2.

Minimum stent area (MSA) was reported by three studies [10, 16, 17]. MSA was higher in OCT group. OCT-guided group had lower percentage of malapposed stent and uncovered strut (Table 2).

There was no difference in MACE between angiography plus OCT and angiography alone arms (2.5 vs. 2.0% OR 1.26; 95% CI 0.40–3.99; $P=0.69$; $I^2=5\%$) (Fig. 2a). No difference was noted between the two arms in all-cause mortality (0.2 vs. 0% OR 3.03; 95% CI 0.12–75; $P=0.5$; $I^2=$not applicable) (Fig. 2b). Rate of myocardial infarction was similar between the two arms (1 vs. 0.2% OR 2.21; 95% CI 0.39–12.49; $P=0.3$; $I^2=0\%$) (Fig. 2c). Similarly, there were no differences in the rate of target vessel revascularization (1.6 vs. 1.2% OR 1.36; 95% CI 0.4–4.4; $P=0.6$; $I^2=0\%$) (Fig. 3a) and stent thrombosis (0.2 vs. 0.5% OR 0.7; 95% CI 0.11–4.51; $P=0.7$; $I^2=0\%$) (Fig. 3b) between the two arms.

Four randomized studies report on fluoroscopic time [10, 12, 16, 18]. Angiography plus OCT-guided group was associated with longer fluoroscopic time [weighted mean difference (WMD) 3.17 min; 95% CI 2.69–3.64; $P=0.04$; $I^2=64\%$] (Fig. 4a). Combination group required significantly higher amount of contrast volume (WMD 60.4 ml; 95% CI 21.5–99.2; $P<0.002$; $I^2=99\%$) (Fig. 4b). However, both these results revealed high heterogeneity which remained persistent even after reanalyzing the overall effect after removing one study at a time. Rate of procedural complications and acute kidney impairment was similar in two groups.

Sensitivity analysis and subgroup analysis

As pre-specified in our methodology, we performed meta-analysis using random effect model. However, as there was extremely low heterogeneity in primary outcomes, we also analyzed data using fixed effect model. Final results did not differ between two models for all the outcomes.

We also did subgroup analysis based on the duration of follow-up (<6 vs. >6 months). There was no difference in major outcomes between two arms based on the length of follow-up.

Discussion

Imaging studies like IVUS and OCT have been increasingly used for optimizing PCI outcomes. While a few studies have suggested that IVUS could reduce repeat revascularization rates after BMS implantation [19], stent thrombosis after DES implantation [20], and mortality after PCI for unprotected left main disease [17], other have not confirmed such findings [21, 22]. OCT may have distinct practical advantages compared both to angiography and to IVUS, given its ability to identify lumen contours, struts, and nearby structures correctly.

Fewer MACE in OCT group was seen in studies by Kim et al. [17] and Antonsen et al. [16], while others [10, 12, 18] did not show similar findings. The reason behind fewer MACE in OCT group in studies by Kim et al. [17] and Antonsen et al. [16] could be the inclusion of high-risk patients. Antonsen et al. [16] included more than 70% of B2/C ACC–AHA-type coronary lesions, while Kim et al. [17] had >90% of such population. However, study by Kala et al. [18] and ILUMIEN III [10] excluded such population, while DOCTORS [12] included majority of ACC/AHA lesions A and B1 types. The largest non-randomized study ($n=670$) by Prati et al. [23] showed both mortality and MACE benefit for OCT group. This study also included very high-risk patients with >70% of B2 and C types lesion and significant proportion of left main disease, (8 vs. 22%, $P=0.009$). Previous studies on IVUS demonstrated beneficial clinical effect in subset of complex coronary lesions [24,

Table 1 Characteristics of included studies

	Meneveau et al. (DOCTORS trial) [11]	Ali et al. (ILUMIEN III trial) [9]	Kim et al. [16]	Antonsen et al. [15]	Kala et al. [17]
Journal/year	Circulation/2016	Lancet/2016	Rev Esp Cardiol/2015	Circ Cardiovasc Intervention/2015	Int J Cardiol 2017
Type of study	RCT	RCT	RCT	RCT	RCT
Follow-up (months)	6	12 (30-day outcomes reported in the study)	6	6	9
N/n	120/120	146/158	51/50	45/40	105/96
Participating countries	France	USA, Japan, and 6 European countries %	Korea	Denmark	Czech Republic
Inclusion	18–80 years with NSTEMI and with indication for angioplasty with stent implantation of target lesion (single lesion on culprit without diffuse disease)	≥ 18 years undergoing PCI with angina, silent ischaemia, NSTEMI, or STEMI > 24 h after initial diagnosis	≥ 20 and significant coronary de novo lesion(s), ≥ 70% diameter stenosis on visual estimation), and a native coronary artery with a reference vessel diameter between 2.5 and 4.0 mm that could be covered by a single stent	≥ 18 and < 80 with NSTEMI or a de novo culprit lesion (≥ 50% diameter stenosis) in the coronary arteries, and PCI with stent was indicated	18–85 years of age STEMI patients treated with primary PCI
Exclusion	Left main, in-stent restenosis, h/o CABG, cardiogenic shock, one of more other lesions, persistent ST elevation	Left main disease, ostial right lesion, bypass graft occlusion, chronic total occlusion, two-stent bifurcation, in-stent stenosis	Left main disease, total occlusion, graft occlusion, bifurcation lesion requiring two stents, EF < 35%, ESRD, life expectancy < 1 year, prior DES within last 3 months	Left main, extremely narrowed tortuous coronary arteries, long lesions (> 45 mm), bifurcation lesions, reference vessel diameter(s) > 3.5 mm, life expectancy < 12 months, and renal failure	Left main, ostial disease, cardiogenic shock
Primary end points	Functional result of PCI as measured by FFR	Post-PCI minimum stent area	% Of uncovered struts	Difference in % of uncovered struts between two groups	Assessment of possible merits of OCT guidance in primary PCI
Secondary end points	Procedural complications and safety	Procedural MACE	% Of malapposed struts, MACE	% of malapposed struts at baseline, at 6-month follow-up, and % of struts being both malapposed and uncovered at 6-month follow-up	NA
Disease	NSTEMI	Angina, silent ischaemia, STEMI after 24 h	Stable angina, ACS	NSTEMI and silent ischaemia	STEMI
Age (*n*/*n*)	60/60	67/66	61/58	62/61	59/57
Male % (*n*/*n*)	75/79	73/69	72/78	68/72	87/83
HTN (%)	41/55	75/78	49/54	56/56	52/50
DM (%)	15/21	29/33	31/32	10/16	26/17
HL (%)	46/49	77/73	72/66	38/44	NA

Table 1 (continued)

	Meneveau et al. (DOCTORS trial) [11]	Ali et al. (ILUMIEN III trial) [9]	Kim et al. [16]	Antonsen et al. [15]	Kala et al. [17]
Current smoker (%)	42/39	24/18	29/32	36/46	59/64
No. of diseased vessels = 1 (%)	73/65	NA	NA	NA	91/88
= 2 (%)	20/30	NA	NA	NA	8/11
= 3(%)	6/10	NA	NA	NA	2/0
Right coronary artery (%)	36/31	22/22	18/17	46/38	52/48
Circumflex (%)	23/21	21/27	25/21	14/14	12/16
Left ant descending (%)	50/46	57/51	55/60	40/48	32/39
Types of stent (%)	NA	Everolimus 60/65 Zotarolimus 35/27 Bio-and sirolimus 5/8	Zotarolimus-eluting stent	Biolimus-eluting	Biolimus- or everolimus –eluting

N/n angiography-guided/OCT-guided, *NA* not available, *PCI* per cutaneous coronary intervention, *FFR* fractional flow reserve, *MACE* major adverse cardiac events, *h/o* history of, *HTN* hypertension, *DM* diabetes mellitus, *HL* hyperlipidemia, *ACS* acute coronary syndrome, *ESRD* end stage renal disease, *NSTEMI* non ST elevation myocardial infarction, *STEMI* ST elevation myocardial infarction, *BMS* bare metal stent, *DES* drug-eluting stent

25]. Like IVUS benefits of OCT in reducing MACE may be more evident in patients with complex coronary lesions. The disparity in MACE outcome between randomized and non-randomized studies could be because of two reasons. First, this may be due to a real effect not observed in the smaller pooled randomized study population. Second, it can be as a result of selection bias inherent in non-randomized approach, wherein patients whose clinical features may portend a superior clinical outcome are preferentially selected for specific intervention.

The rate of MACE in OCT-guided PCI might be higher than reported for IVUS-guided PCI [26]. This is likely related to increase procedural MACE associated with OCT compared to IVUS. It was observed that although follow-up stent area was similar, the post-procedure minimum stent area (MSA) was larger by IVUS compared with OCT [27]. MSA is an important determinant of freedom from early and late MACE after stenting [3, 25]. However, some consider MSA to be a relative measure of stent expansion, because IVUS measurements are typically larger than those by OCT [6, 27, 28].

One mechanism by which OCT is beneficial is that OCT guidance can disclose additional procedural issues not recognized by angiography leading to additional intervention. Findings resulting from OCT led to additional interventions in as many as about 35% of the subjects in the included studies [16, 18, 23]. The use of OCT in the setting of acute coronary syndromes may render visible certain features that characterize unstable lesions, but which often cannot be seen by angiography alone [29]. Other mechanism of benefit with OCT guidance could be related to identification of edge dissections. Rate of edge dissection in OCT group in the included studies range from 7 to 45% [10, 12, 23, 30]. Deeper dissections may be associated with an increased risk of target lesion revascularization and adverse 1-year outcome [31]. However, increased discriminatory power to detect edge dissection in OCT group did not translate into favorable target vessel revascularization for OCT group in our meta-analysis. This is likely driven by identification of minor non-flow-limiting dissections which are benign and have no clinical significance [32].

Contrast media volume is a well established, dose-dependent risk factor for contrast-induced nephropathy, which is associated with an increased risk of in-hospital mortality and poor long-term outcomes [33]. Fluoroscopic time and contrast material were higher in OCT group, but none of the patients in OCT group were known to develop contrast-induced nephropathy.

A recently published meta-analysis by Buccheri et al. [8] comparing imaging-guided vs. angiography-guided PCI, consisting of both randomized and non-randomized studies, found cardiovascular death reduction by IVUS (in both randomized and observational) and OCT (in only observational

Table 2 Outcome of interest pooled from included studies

	Meneveau et al. (DOCTORS trial) [11]	Ali et al. (ILUMIEN III trial) [9]	Kim et al. [16]	Antonsen et al. [15]	Kala et al. [17]
Percent of uncovered strut	NA	NA	4.51 (5.43)/1.60 (1.84)	9 (5.5–14.5)/4.3 (1.2–9.8)**	16.7 (15.8)/12.7 (13)
Minimum stent area	NA	5.49 (4.39–6.51)/5.79 (4.54–7.34)**	6.61 (2.27)/6.66 (2.18)	5.7 (1.9)/6.2 (1.6)	NA
Stent malapposition	NA/38	83/58	18/9	16/15	NA
Fluoroscopy time	9 (6–13)/12.7 (8.5–17)**	13 (9–20.2)/16 (10–24)**	NA	6.9 (4.9–10.3)/9.9 (6–17.1)**	7.2 (2.5)/10.2 (3.5)
Contrast media vol uses (ml)	120 (90–160)/190 (140–250)**	183 (140–250)/222 (164–285)**	NA	110 (100–152.5)/150 (100–255)**	164 (53.3)/230.7 (77.1)
Stent length (mm)	17.3 (5.5)/17.9 (5.6)	20 (16–30)/23.5 (15–32)**	17.6 (4.3)/18 (3.9)	20.1 (8.4)/22.6 (9)	NA
All-cause mortality	0/1	0/0	NA	NA	0/0
MI	1/1	0/2	NA	NA	0/1
MACE	NA	1/4	3/2	2/0	1/3
TVR	1/2	1/1	2/2	NA	1/2
ST	0/0	0/1	1/0	1/0	NA
AKI	2/2	0/0	NA	NA	0/0
Procedural complication	7/7	1/3	NA	NA	0/0

N/n angio group/OCT group, *NA* not available, *AKI* acute kidney injury

**Values are median (inter-quartile range)

[#]Procedural complications = dissection, perforation and abrupt closure

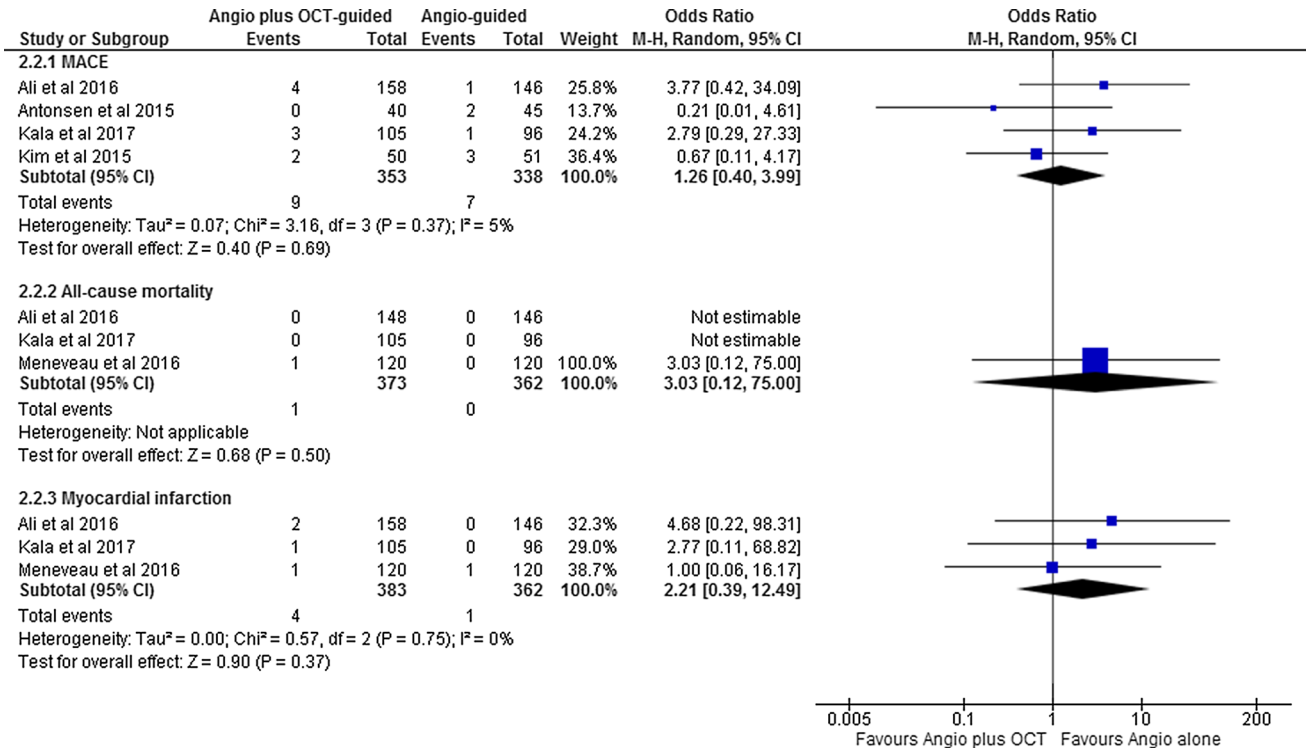

Fig. 2 Forest plot of MACE (**a**), all-cause mortality (**b**) and MI (**c**)

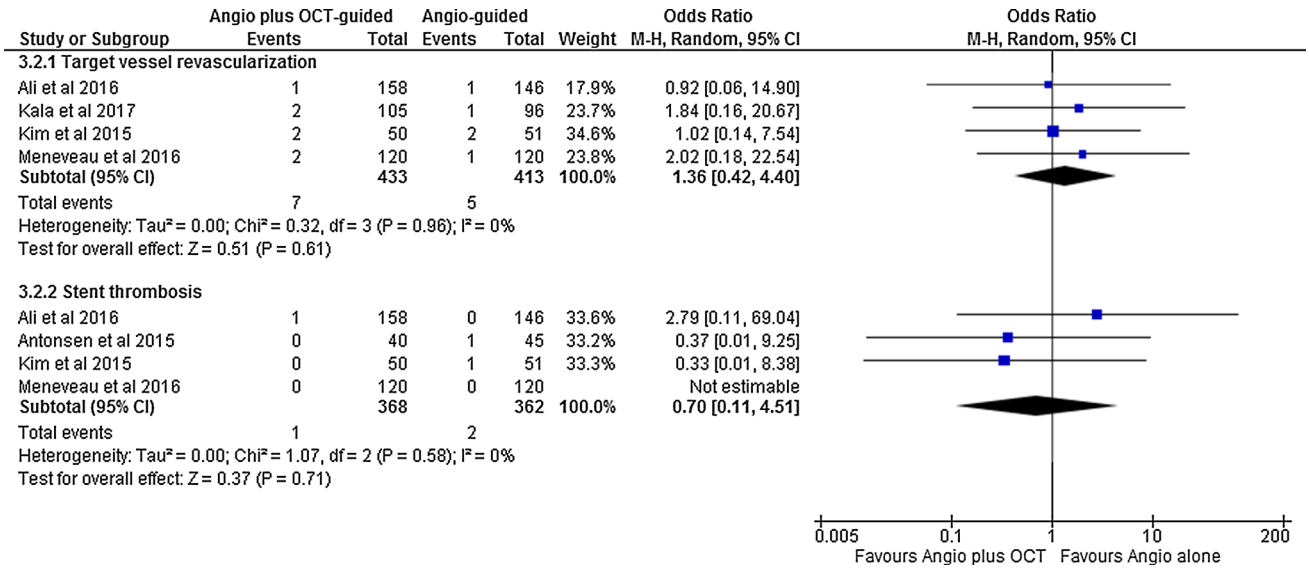

Fig. 3 Forest plot of target vessel revascularization (**a**) and stent thrombosis (**b**)

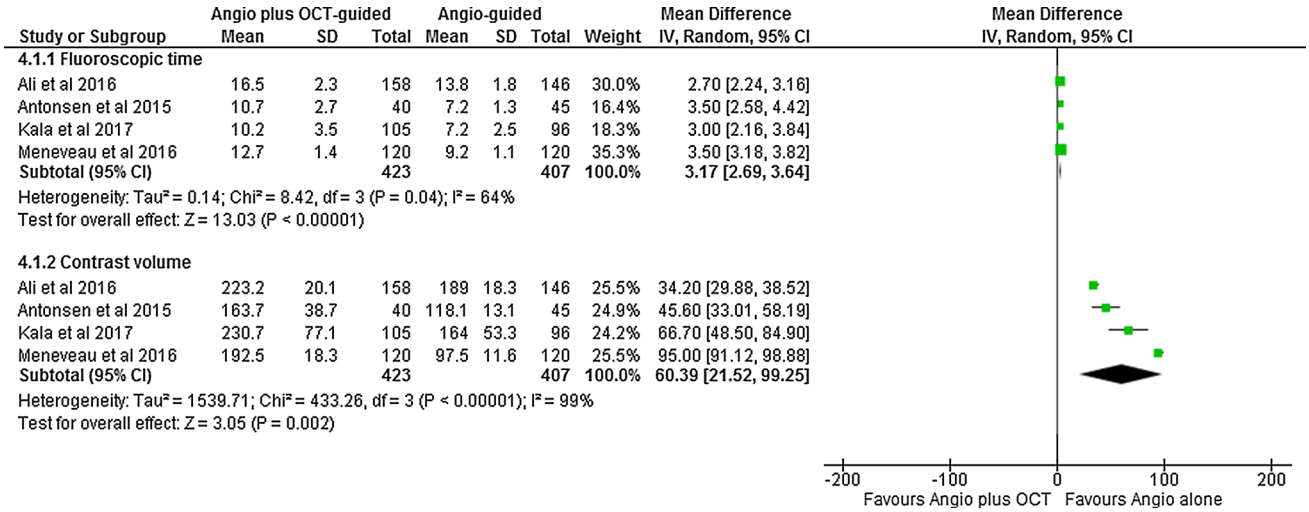

Fig. 4 Forest plot of fluoroscopic time (**a**) and contrast volume (**b**)

studies). Unlike, the study by Buccheri et al. our study is more comprehensive with inclusion of five RCTs (vs. 2 RCTs) and provides higher level of evidence about the outcomes of OCT-guided PCI. Contrary to results of Buccheri et al., we did not find any clinical benefits associated with addition of OCT to angiography-guided PCI. There could be a few reasons behind this—first, our meta-analysis excluded non-randomized studies which drove cardiovascular death reduction in the study by Buccheri et al. Second, our included studies had varied follow-up duration with the longest follow-up duration being 1 year. The benefits of OCT such as change in operator decision making, an increase in stent expansion, are unlikely to result in difference in short-term MACE. More meaningful endpoint would be long-term MACE which could not be assessed in our study.

Our meta-analysis has several limitations. Short follow-up duration, variable inclusion and exclusion criteria, limited number of RCTs, and lack of patient level data are major limitations. Lack of long-term outcomes on freedom from symptoms of ischemia and absence of inducible ischemia in revascularized territory are other limitations.

Conclusion

Our meta-analysis found that routine use of OCT-guided PCI is not associated with better clinical outcomes compared to angiography alone-guided PCI. Our conclusion is drawn from small number of events noted in the included studies with short follow-up.

Existing guidelines recommended OCT as investigational in terms of improving clinical outcomes associated with the performance of PCI due to lack of prospective randomized studies demonstrating clinical improvements [34]. Though more RCTs have been added, since the publication of this guideline small number of patients enrolled in these trials may not provide adequate evidentiary base to draw firm conclusion. Hence, further large studies with hard clinical end points are needed to reveal if there is any clinical superiority of routine OCT-guided PCI. Future studies should probably focus on the role of OCT guidance in high-risk coronary lesions.

Author contributions Conception and design: SPS and KD. Provision of study material: SPS and KD. Collection and assembly of data: all authors. Data analysis and interpretation: all authors. Manuscript writing: all authors. Final approval of manuscript: all authors.

Funding None.

Compliance with ethical standards

Conflict of interest The authors declare that there is no conflict of interest.

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