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INTRAVASCULAR IMAGING (A. G. TRUESDELL, SECTION EDITOR)

Better Is the Evolution of Good: How IVUS and OCT Have Transformed PCI

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Abstract

Purpose of Review We seek to provide a focused appraisal of the most recent outcomes data for intravascular ultrasound (IVUS) and optical coherence tomography (OCT).

Recent Findings There are multiple randomized control trials and meta-analyses investigating the effects of these two intravascular imaging (IVI) modalities on clinical decision-making and long-term clinical outcomes in percutaneous coronary intervention (PCI). While the effects of IVUS have been studied for decades, OCT is a newer form of IVI with less experience and data on its use in clinical practice.

Summary IVUS-guided PCI has beneficial effects on mortality, stent thrombosis, target lesion/target vessel revascularization, and major adverse cardiac events when compared to angiography alone. While less data exists for OCT-guided PCI, early studies suggest it is at least non-inferior to IVUS for many of the same outcomes. However, future investigations should focus on how clinical outcomes are changed by these two IVI modalities when compared head-to-head.

Keywords Clinical outcomes · Coronary angiography · Drug eluting stent · Intravascular imaging · Intravascular ultrasound · Optical coherence tomography · Optical frequency domain · Percutaneous coronary intervention

Abbreviations

ACCF	American College of Cardiology Foundation
AHA	American Heart Association
BMS	Bare metal stent
CTO	Chronic total occlusion
DES	Drug-eluting stent
IVI	Intravascular imaging
IVUS	Intravascular ultrasound
MA	Meta-analysis
MACE	Major adverse cardiac events
MI	Myocardial infarction
OCT	Optical coherence tomography
PCI	Percutaneous coronary intervention
RCT	Randomized control trial
SCAI	Society for Cardiovascular Angiography and Interventions
ST	Stent thrombosis
STEMI	ST-elevation myocardial infarction
TLR	Target lesion revascularization
TVF	Target vessel failure

This article is part of the Topical Collection on *Intravascular Imaging*

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TVR Target vessel revascularization
• Important reference
•• Very important reference

Introduction

Coronary angiography is considered the gold standard in the assessment of coronary anatomy [1]. However, its major limitation is that it produces a two-dimensional "lumenogram" of a three-dimensional structure. Multiple orthogonal views with visual estimation are used to ascertain information about the patient's coronary arteries. This approach has several limitations and there is well-established inter- and intra-observer variability in the reporting of coronary angiograms leading to potential variability in management strategies [2, 3]. Intravascular imaging (IVI) can help reduce the variability that exists in the interpretation of stenosis severity and lesion morphology based on angiographic assessment alone. IVI helps overcome some of the limitations of conventional angiography by providing more information about the vessel wall and plaque burden (Table 1). Currently, intravascular ultrasound (IVUS) and optical coherence tomography (OCT) are the most widely used forms of IVI. In this review, we aim to provide a focused summary of the most recent clinical outcomes data for intravascular imaging modalities, with an emphasis placed on randomized clinical trial data as well as large meta-analyses.

Intravascular Imaging Modalities

Intravascular Ultrasound

IVUS is a sound-based technology that uses a specially designed catheter with an ultrasound probe to visualize coronary anatomy. Real-time 360° cross-sectional images are obtained and used to provide detailed information about the lumen, vessel size, and plaque morphology [4]. There are two major transducer designs: (1) the mechanical single-element rotating device and (2) the electronic phase array [5].

The role of IVUS in the era of bare metal stents (BMS) is well established with reductions in major adverse cardiac events (MACE) and repeat revascularization, predominantly driven through reductions in in-stent restenosis and target vessel revascularization (TVR) [6–14]. There is an abundance of literature investigating the use of IVUS in contemporary PCI practice. Most early research was based on observational registries [13, 15–18]. However, there are now several randomized control trials (RCTs) and meta-analyses (MAs) supporting the use of IVUS-guided PCI in complex lesions and high-risk patient subsets (long-lesions, bifurcation lesions, chronic total occlusions [CTOs], and unprotected left main disease) [19–27].

Optical Coherence Tomography

OCT is a newer IVI modality that uses light-based technology to generate higher-resolution images when compared to IVUS, however with less robust clinical outcomes data [28–31]. The high resolution permits detailed visualization of intraluminal and transmural coronary anatomy, overcoming some of the limitations of coronary angiography while providing nuanced details not captured by IVUS [32••]. The unique features of OCT allow for visualization of the fibrous cap and can assess the depth of calcium in a coronary lesion. These characteristics may alter patient management by helping identify vulnerable plaques and assisting the operator in lesion preparation with the use of atherectomy as indicated [33–36].

Cardiovascular and All-Cause Mortality

IVUS and DES Trials

Multiple recent RCTs and MAs support the role of IVUS-guided DES implantation in reducing cardiovascular mortality (Table 2). Prior studies focused on the role of IVUS in high-

Table 1 Comparison of angiography and intravascular imaging modalities. [4]

Angiography	Intravascular Imaging
• 2-Dimensional	• 360° view
• Planar	• Tomographic and sagittal
• Shadow of lumen	• Visualization of shape and location
• Wall structure not imaged	• Visualization of inner wall structure and morphology
• Vessel is seen for short time period during contrast injection	• Confluent imaging: the whole vessel can be imaged
• Quantitative coronary angiography with mistakes	• Spatial imaging precise assessment

Table 2 Outcomes data of included studies for IVUS and OCT as compared to angiography and one other

	Study	Design	Year	Number of patients	Stent type	Follow-up, mo	All-cause death (95% CI, *p* value)	CV mortality (95% CI, *p* value)	MI (95% CI, *p* value)	ST (95% CI, *p* value)	TLR/TVR (95% CI, *p* value)	MACE (95% CI, *p* value)
IVUS v. Angiography	Darmoch et al. [40•]	MA	2020	27,610	DES/BMS	6–64	–	RR 0.63 (0.54–0.73, < 0.001)	RR 0.71 (0.58–0.86, 0.09)	RR 0.57 (0.41–0.94, 0.04)	RR 0.81 (0.70–0.79, 0.06)	–
	Gao et al. [43]	MA	2019	4724	DES	16.7	RR 0.78 (0.46–1.31, 0.34)	RR 0.49 (0.26–0.92, 0.03)	RR 0.79 (0.54–1.17, 0.24)	RR 0.45 (0.23–0.87, 0.02)	– RR 0.59 (0.44–0.80, 0.001) RR 0.58 (0.42–0.80, 0.001)	RR 0.61 (0.49–0.74, < 0.001)
	Elgendy et al. [42]	MA	2019	5060	DES	12–24	–	OR 0.44 (0.26–0.75, 0.003)	OR 0.55 (0.32–0.94, 0.03)	OR 0.44 (0.24–0.79, 0.006)	OR 0.57 (0.42–0.77, < 0.001)	–
	Kumar et al. [44]	MA	2019	5352	DES	12–24	–	OR 0.45 (0.25–0.80, 0.007)	OR 0.83 (0.54–1.28, 0.39)	OR 0.47 0.24–0.94,0.03)	– OR 0.56 (0.41–0.77, 0.0004)	–
	Malik et al. [41]	MA	2019	5007	DES	12–24	–	RR 0.51 (0.27–0.96, 0.04)	RR 0.86 (0.58–1.29, 0.47)	RR 0.50 (0.24–1.04, 0.06)	– RR 0.59 (0.44–0.80, < 0.01 RR 0.59 (0.43–0.81, < 0.01)	RR 0.63 (0.51–0.77,< 0.0-1)
	Liu et al. [69]	RCT	2019	336	DES	12	–	1.8% vs. 5.9% (0.048)	11.4% vs. 13.6% (0.478)	1.2% vs. 3.0% (0.246)	1.2% vs. 3.0% (0.239) 4.2% vs. 8.9% (0.068)	13.2% vs. 21.9% (0.031)
	ULTIMATE [39••]	RCT	2018	1488	DES	12	HR 0.584 (0.267–1.275, 0.17)	0.497 (0.170–1.453, 0.19)	HR 0.634 (0.246–1.636, 0.34)	HR 0.199 (0.023–1.704, 0.10)	HR 0.466 (0.211–1.030, 0.05) 0.514 (0.248–1.066, 0.07)	–
	Buccheri et al. [38•]	MA	2017	14,137	DES/BMS	1–36	OR 0.74 (0.58–0.98)	OR 0.47 (0.32–0.66)	OR 0.72 (0.52–0.93)	OR 0.42 (0.20–0.72)	OR 0.74 (0.58–0.90)	OR 0.79 (0.67–0.91)
	ILUMIEN III [32••]	RCT	2016	292	DES	1	0% vs. 0%	–	1% vs. 0%	0% vs. 0%	– 0% vs. 1%	1% vs. 1%
	Zhang et al. [27]	MA	2016	31,283	DES	9–48	OR 0.62 (0.54–0.72, < 0.001)	–	0.67 (0.56–0.80, < 0.001)	OR 0.58 (0.47–0.73, < 0.001)	– OR 0.77 (0.67–0.89, 0.005) OR 0.85 (0.76–0.95, < 0.001)	OR 0.76 (0.70–0.82, < 0.001)
	IVUS-XPL [20]	RCT	2015	1400	DES	12	–	HR 0.60 (0.14–2.52, 0.48)	0% vs. 0.1% (0.32)	HR 1.00 (0.14–7.10, > 0.99)	HR 0.51 (0.28–0.91, 0.02	HR 0.48 (0.28–0.83, 0.007)
	CTO-IVUS [21]	RCT	2015	402	DES	12	HR 0.67 (0.11–3.99, 0.66)	0% vs. 1% (0.16)	0% vs. 1% (0.16)	0% vs. 3% (0.11)	– HR 0.62 (0.20–1.89, 0.40) HR 0.48 (0.17–1.42, 0.19)	HR 0.35 (0.13–0.97, 0.035)
	Tan et al. [22]	RCT	2015	123	DES	24	–	3.3% vs. 3.2% (0.648)	–	1.6% vs. 3.2% (0.568)	8.2% vs. 16.4% (0.045)	12.8% vs. 27.3% (0.049)
	AIR-CTO [23]	RCT	2015	230	DES	24	5.2% vs. 6.1% (0.775)	2.6% vs. 4.3% (0.557)	17.4% vs. 13.0% (0.463)	2.6% vs. 6.9% (0.162)	7.6% vs. 10.4% (0.484)	21.7% vs. 25.2% (0.641)

Table 2 (continued)

	Study	Design	Year	Number of patients	Stent type	Follow-up, mo	All-cause death (95% CI, *p* value)	CV mortality (95% CI, *p* value)	MI (95% CI, *p* value)	ST (95% CI, *p* value)	TLR/TVR (95% CI, *p* value)	MACE (95% CI, *p* value)
											7.8% vs. 12.2% (0.380)	
OCT vs. Angiography	Kuku et al. [46•]	MA	2018	1753	DES/BMS	6–12	–	OR 0.40 (0.18–0.90, 0.03)	OR 0.70 (0.42–1.16, 0.17)	OR 1.17 (0.40–3.43, 0.77)	OR 1.07 (0.48–2.38, 0.86)	OR 0.70 (0.49–1.00, 0.05)
	Buccheri et at. [38•]	MA	2017	2396	DES/BMS	1–23	OR 0.59 (0.29–1.20)	OR 0.31 (0.13–0.66)	OR 0.79 (0.44–1.40)	OR 0.39 (0.10–1.20)	– OR 0.66 (0.35–1.20)	OR 0.68 (0.49–0.97)
	ILUMIEN III [32••]	RCT	2016	304	DES	1	0% vs. 0%	–	1% vs. 0% (0.50)	1% vs. 0% (1)	– 1% vs. 1% (1)	3% vs. 1% (0.38)
	DOCTORS [70]	RCT	2016	240	DES/BMS	6	0.8% vs. 0% (1)	OR 1.00 (0.06, 16.17, 1.00)	0.8% vs. 0.8% (1)	0% vs. 0%	– 1.6% vs. 0.8% (0.50)	2.5% vs. 1.6% (1)
	Sheth et al. [59]	Obs	2016	642	DES/BMS	12	–	HR 0.49 (0.16–1.47, 0.20)	HR 0.90 (0.31–2.58, 0.84)	HR 1.58 (0.42–5.90, 0.49)	– HR 0.91 (0.44–1.85, 0.79)	HR 0.76 (0.43–1.34, 0.34)
	Iannaccone et al. [71]	Obs	2016	540	–	23	3% vs. 4% (0.15)	–	6% vs. 6% (0.86)	0% vs. 2.7% (0.26)	2% vs. 3% (0.92) 2% vs. 4% (0.15)	11% vs. 16% (0.06)
	CLI-OPCI [47•]	Obs	2012	670	DES/BMS	12	3.3% vs. 6.9% (0.035)	1.2% vs. 4.5% (0.010)	5.4% vs. 8.7% (0.096)	0.3% vs. 0.6% (1.0)	3.3% vs. 3.3% (1.0)	9.6% vs. 15.1% (0.034)
OCT vs. IVUS	Kuku et al. [46•]	MA	2018	1028	DES	12	–	OR 0.56 (0.12–2.70, 0.47)	OR 0.56 (0.12–2.70, 0.47)	OR 0.43 (0.06–2.95, 0.39)	– OR 0.99 (0.45–2.18, 0.99)	OR 0.89 (0.46–1.73, 0.73)
	Buccheri et at. [38•]	MA	2017	1349	DES	1–12	–	OR 0.66 (0.27–1.50)	OR 1.10 (0.60–2.10)	OR 0.93 (0.24–3.40)	– OR 0.88 (0.47–1.60)	OR 0.87 (0.61–1.30)
	ILUMIEN III [32••]	RCT	2016	304	DES	1	0% vs. 0%	–	1% vs. 1% (1)	1% vs. 0% (1)	– 1% vs. 0% (1)	3% vs. 1% (0.69)
	OPINION [47•]	RCT	2016	417	DES	12	–	HR 0.98 (0.00–18.86, 0.99)	HR 0.65 (0.05–5.74, 0.98)	HR 0.49 (0.01–9.46, 0.99)	HR 0.90 (0.35–2.25, 0.97) HR 1.16 (0.57–2.41, 0.78)	HR 0.84 (0.35–1.98, 0.81)
	Kim et al. [60]	Obs	2016	228	DES	12	–	1.8% vs. 2.6% (1.000)	0.0% vs. 0.9% (1.000)	0.0% vs. 0.9% (1.000)	1.8% vs. 0.9% (1.000) –	3.5% vs. 3.5% (1.000)

BMS bare metal stent, *CI* confidence interval, *CV* cardiovascular, *DES* drug eluting stent, *HR* hazard ratio, *IVUS* intravascular ultrasound, *MACE* major adverse cardiac events, *MI* myocardial infarction, *Obs* observational study, *OCT* optical coherence tomography, *OR* odds ratio, *RR* relative risk, *ST* stent thrombosis, *TLR* target lesion revascularization, *TVR* target vessel revascularization, – unavailable or uninterpretable data

risk patients with complex lesion subsets where the risk of stent underexpansion, malapposition, and edge dissection are high [19–21, 23–27, 37, 38•]. For example, the randomized, multicenter trial, IVUS-XPL, conducted in 1400 patients with long coronary lesions (implanted stent ≥ 28 mm in length), demonstrated that IVUS-guided everolimus-eluting stent implantation resulted in a significantly lower rate of the composite endpoint of MACE at 1-year when compared to angiography alone (Table 2). However, these results could not be generalized to patients with lower risk, more straightforward lesions until the results of the ULTIMATE trial, the largest RCT in IVUS guidance which included 1488 all-comer patients. In this study, use of IVUS was shown to decrease 12-month target vessel failure (TVF) by 47% with reduced cardiac death rate when compared to coronary angiography alone [39••]

These findings are reinforced by the largest IVUS-guided PCI MA of 27,610 patients. This was conducted by Darmoch et al. who performed pooling of 10 observation studies and 9 RCTs (Table 3). Compared to angiography alone, IVUS guidance was associated with decreased risk of cardiac death (relative risk reduction of 33%; $p < 0.001$) [40•] Despite this study's use of observation registries and RCTs that utilized BMS, multiple additional MAs inclusive of DES RCTs alone have shown similarly favorable results (Table 2) [41–44].

OCT and DES Trials

Compared to IVUS, there is less volume of outcomes data for OCT (Table 2). CLI-OPCI, an observational study of 670 patients, was the first comparing angiography with OCT guidance. At 12 months follow-up, the OCT-guidance group had reduced rates of cardiac death when compared to angiography alone (Table 2). However, their results were limited by the retrospective design of the study and the fact that 60% of patients in the OCT group received DES compared to only 40% in the angiography group [45].

Kuku et al. published the latest MA of 6 studies in 2017 which included a total of 2781 patients, 1753 of which constituted the OCT vs. angiography group (Table 4). They demonstrated that OCT-guided PCI had statistically significant reductions in cardiac death when compared to angiographic guidance alone (OR 0.40; $p = 0.03$) [46•]

OCT Vs. IVUS and DES Trials

There are relatively few studies evaluating outcomes data for these two IVI modalities when compared head-to-head (Table 2). In a comparison of OCT vs. IVUS guidance in the meta-analysis by Kuku and colleagues ($n = 1028$), no statistically significant results were observed for all outcomes, including cardiac death [46•]. OPINION, the only RCT comparing OCT-guided with IVUS guidance included in this MA (Table 5), demonstrated non-inferiority of optical frequency domain imaging relative to IVUS-guided PCI for the primary endpoint of TVF (composite of cardiac death, target vessel-related MI, and clinically driven TVR). However, very low rates of cardiac death were observed in both groups ($n = 0$ vs. 1, respectively) [47•]

ILUMIEN III: OPTIMIZE PCI, which randomized 450 subjects, carried out a three-way comparison of OCT, IVUS, and angiography for guiding DES placement. They demonstrated similar post-PCI minimum stent area between OCT and IVUS guidance. The study was not designed to assess clinical outcomes in the groups at long-term follow-up. [32•]

Finally, in a large, prospective, observation registry of 87,166 patients with median follow-up of 4.8 years, OCT-guided PCI showed a significantly reduced mortality rate when compared to angiography alone (9.60% vs. 16.80%; $p < 0.0001$), whereas no difference was found in the matched OCT and IVUS cohorts (8.96% vs. 10.20%; $p = 0.12$). [48]

Summary

- Multiple MAs and RCTs support the role for IVUS-guided DES implantation in reducing cardiovascular and all-cause mortality
- Early clinical studies suggest OCT guidance is likewise associated with mortality benefits

Myocardial Infarction

IVUS and DES Trials

Whereas prior MAs suggested a reduction in MI associated with IVUS guidance, these studies were based on smaller groups of RCTs and are not supported by more recent data. While MAs that have included a larger number of RCTs have found a trend towards reduction in MI with IVUS guidance, most fail to demonstrate statistical significance (Table 2) [41, 43]. For example, Kumar et al., which included 11 RCTs (Table 3), failed to show statistically significant reductions in MI with IVUS use among the 5352 patients included in their study (1.64% vs. 2.03%; $p = 0.69$) [44]. These findings would suggest earlier claims of lower MI rates with IVUS guidance were primarily driven by observational studies likely due to residual confounding.

In the largest MA of IVUS-guided PCI ($n = 27,610$), Darmoch et al. demonstrated lower MI risk associated with IVUS guidance (with a number needed to treat of 91 to prevent 1 MI). However, their study included 10 observation studies (Table 3). [40•]

Table 3 Included studies of MAs comparing IVUS-guided PCI to angiography alone

Meta-analysis		Buccheri et al. 2017 [38•]	Malik et al. 2019 [41]	Kumar et al. 2019 [44]	Elgendy et al. 2019 [42]	Gao et al. 2019 [43]	Darmoch et al. 2020 [40•]
BMS RCTs	RESIST 1998	X					
	CRUISE 2000	X					
	OPTICUS 2001	X					X
	Gaster et al. 2003	X					
	TULIP 2003	X					
	DIPOL 2007	X					X
	AVID 2009	X					X
DES RCTs	HOME DES IVUS 2010	X	X	X	X	X	X
	AVIO 2013	X	X	X	X	X	
	RESET 2013	X	X	X	X	X	X
	IVUS-XPL 2015	X	X	X	X	X	X
	AIR-CTO 2015	X	X	X	X	X	X
	CTO-IVUS 2015	X	X	X	X	X	X
	Tan et al. 2015	X	X	X	X	X	
	Zhang et al. 2016		X	X	X	X	
	ULTIMATE 2018		X	X	X	X	X
	ILUMIEN III: OPTIMIZE PCI 2016	X	X	X			
	Liu et al. 2019			X	X		
Observational	Roy et al. 2008						X
	MAIN-COMPARE 2009	X					
	MATRIX 2011	X					X
	Kim et at. 2005	X					
	Chen et al. 2012	X					X
	Wakabayashi et al. 2012	X					X
	EXCELLENT 2013	X					X
	De La Torre Hernandez et al. 2014	X					X
	Gao et al. 2014	X					X
	Hong et al. 2014	X					X
	Witzenbichler et al. 2014						X
	Choi et al. 2019						X

BMS bare metal stent, *DES* drug eluting stent; *MA* meta-analysis, *IVUS* intravascular ultrasound, *PCI* percutaneous coronary intervention, *RCT* randomized control trial

OCT and DES Trials

OCT offers a more precise visualization of the important characteristics that help determine plaque vulnerability. Evidence of large lipid burden by OCT and the presence of thin-cap fibroatheroma have been associated with periprocedural-MI [49–52]. A prospective, non-randomized, observational study of procedural practice in 418 patients comparing the impact of OCT on physician decision making, ILUMIEN I, demonstrated lower peri-PCI MI (0 vs. 8.8%) with OCT guidance when compared to angiography alone ($p = 0.023$) [53]. CLI-OPCI II, a retrospective study of 832 patients who underwent post-stenting OCT assessment to expand upon the findings of CLI-OPCI, found suboptimal OCT deployment to be associated with a higher risk of MI when compared to optimal deployment ($p = 0.001$). [54] However, other studies investigating the clinical outcomes of OCT guidance have failed to demonstrate statistical significance for MI reduction (Table 2) [38•, 46•].

Summary

- Despite earlier claims that IVUS guidance is associated with lower rates of MI, these findings may be related to

Table 4 Included studies of MAs comparing OCT-guided PCI to angiography alone

Meta-analysis			
		Bucheri et al. 2017 [38•]	Kuku et al. 2018 [46•]
RCTs	OCT STEMI 2014		X
	DOCTORS 2016	X	X
	ILUMIEN III: OPTIMIZE PCI 2016	X	
Observational	CLI-OPCI 2012	X	X
	Sheth et al. 2016	X	X
	Iannaccone et al. 2016	X	

MA meta-analysis, *OCT* optical coherence tomography, *PCI* percutaneous coronary intervention, *RCT* randomized control trial

the inclusion of observational studies while more recent MAs that included only RCTs do not consistently demonstrate this benefit.

- More high-quality data is needed to make an accurate appraisal of the clinical impact of OCT guidance on MI; early studies suggest OCT may be associated with lower risk.

Stent Thrombosis, Target Lesion Revascularization, and Target Vessel Revascularization

There is overwhelming evidence to support the role for IVUS guidance in reducing the rate of ST and TLR/TVR (Table 2) [38•, 40•, 41, 43, 44, 55]. Furthermore, the findings of ULTIMATE demonstrated IVUS guidance was associated with significant reductions in clinically driven TLR or definite ST ($p = 0.018$), validating that results can be generalized to all-comers [39••] Many studies have concluded that the lower risk of ST and TLR observed with IVUS-guided stent optimization is one of its driving mechanisms for reducing overall adverse events [24, 38•, 56]. However, it has yet to be shown whether OCT guidance is associated with similar findings.

Incomplete strut coverage is one of the important predictors for later thrombotic events and multiple investigations have demonstrated a reduction in the rates of uncovered or malapposed struts associated with OCT guidance [57, 58]. Whether these anatomic observations during OCT-imaging will be translated into clinical benefit by reducing the rates of ST and TLR/TVR is still under investigation.

Using the pre-specified OCT quantitative criteria from CLI-OPCI, CLI-OPCI II found higher rates of stent thrombosis (10.2% vs. 0.7%, $p = 0.001$) associated with a suboptimal deployment [54]. Sheth et al., a 2:1 propensity, score-matched observational study from 2016 comparing OCT-guided PCI vs. angiography alone in 642 STEMI patients, found a trend towards reduced rates of ST and TVR, though their results did not reach statistical significance [59]. Another propensity, score-matched observational study of 228 patients from 2016 comparing OCT vs. IVUS-guided DES implantation, Kim et al. demonstrated a non-significant difference in ST and TLR between the two groups [60]. None of the MAs compiling these results have found statistical differences in either outcome for OCT-guided PCI, both when compared to IVUS guidance or angiography alone (Tables 2, 4, and 5) [38•, 46•].

Summary

- Multiple recent MAs and RCTs support the role for IVUS guidance in lowering the risk of ST and TLR/TVR.
- OCT-derived detection of uncovered struts and determination of optimal stent deployment may prove useful in preventing and predicting adverse cardiac events; however, more studies are needed to determine if the anatomic benefits conferred by OCT guidance can be translated into the clinical benefits of reduced thrombosis risk.

Table 5 Included studies of MAs comparing OCT- vs. IVUS-guided PCI

Meta-analysis			
		Bucheri et al. 2017 [38•]	Kuku et al. 2018 [46•]
RCTs	ILUMIEN III: OPTIMIZE PCI 2016	X	
	OPINION 2016	X	X
Observational	Kim at al. 2016	X	X

MA meta-analysis, *IVUS* intravascular ultrasound, *OCT* optical coherence tomography, *PCI* percutaneous coronary intervention, *RCT* randomized control trial

Major Adverse Cardiac Events

IVUS and DES Trials

While the definition of major adverse cardiac events (MACE) has differed across various studies, multiple MAs and RCTs have found consistent reductions associated with IVUS guidance (Table 2). For example, IVUS-XPL demonstrated that IVUS-guided DES implantation resulted in a significantly lower rate of the composite endpoint of MACE at 1 year (2.9% vs. 5.8%; $p = 0.007$). [20]

Malik et al., in a recent MA of 10 RCTs (Table 3) identified between 2010 and 2018 (5007 patients) comparing IVUS guidance vs. angiography alone, validated these findings demonstrating similar reductions in MACE associated with IVUS use (Table 2) [41].

OCT and DES Trials

When comparing angiography plus OCT to angiography alone, CLI-OPCI demonstrated a significantly lower composite of cardiac death, MI, or repeat revascularization (9.6% vs. 14.8%, $p = 0.044$) associated with OCT guidance [45]. Furthermore, to assess the impact of pre-specified OCT quantitative criteria identified from CLI-OPCI, CLI-OPCI II concluded that suboptimal stent deployment is an independent predictive factor of MACE post-PCI (59.2% vs. 26.9%, $p < 0.001$) [54]. These findings are supported by Kuku et al., which found lower rates for the MACE composite of cardiac deaths, MI, and repeat revascularization among the subgroups comparing OCT guidance to angiography alone (Table 2) [46•].

OCT Vs. IVUS and DES Trials

In the same MA, no significant difference in MACE was observed between the OCT vs. IVUS subgroup (1028 patients) [46•]. Another, larger MA of 31 studies (17,882 patients), Buccheri et al., comparing coronary angiography to OCT and IVUS demonstrated a significant reduction in the odds of MACE with use of either IVI modality whereas no significant differences emerged between OCT and IVUS [38•]

Similarly, OPINION demonstrated non-inferiority of OCT as compared to IVUS for MACE up to 12 months post-procedure and ILUMIEN III: OPTIMIZE PCI found procedural MACE in four (3%) of the 158 patients in the OCT group, one (1%) of the 146 patients in the IVUS group, and one (1%) of the 146 patients randomized to the angiography-alone group (OCT vs. IVUS $p = 0.37$; OCT vs. angiography $p = 0.37$). [47•] [32••]

Summary

- Many RCTs and MAs support the findings of reductions in MACE with IVUS guidance.
- There is a less well-established role for reduction in MACE with OCT guidance, but this IVI modality appears non-inferior to IVUS guidance for this outcome

Safety Outcomes and Future Directions

Despite its proven benefit, use of IVI in routine clinical practice remains low. One report showed that use of intracoronary imaging in the USA increased from 2.1% in 2004 to only 6.6% in 2014, heavily weighted towards IVUS (94.3% IVUS vs. 6.6% OCT) [61]. A potential explanation for this is the belief that there is insufficient data to support its role for routine use. However, the growing body of literature with respect to the above clinical outcomes supports increased, if not routine use of IVI. Angiography has known limitations in assessing vessel size and plaque burden, calcium and eccentricity, and stent expansion and was rated the worst guidance strategy by Buccheri et al., one of the largest MAs described above [38•].

There are multiple other cited reasons to explain the low utilization of IVI [62]. First is the perception of increased cost associated with the use of IVI. However, a study from the Italian healthcare payer perspective demonstrated that IVUS guidance was cost-effective when compared to angiography alone, especially in patients with comorbid conditions who were at higher risk for complications [63].

Secondly, some reference safety concerns surrounding IVI. However, a prospective registry of 2476 IVUS and 1142 OCT patients demonstrated rare complications associated with use of either IVI procedure that did not differ between the two groups. Complications that did occur were self-limiting after retrieval of the imaging catheter or easily treatable in the catheterization laboratory. Furthermore, no major adverse event, prolongation of hospitalization, or permanent patient harm was observed [64]. Although procedure duration is longer in both groups when compared to angiography alone, the differences in fluoroscopy time and total radiation dose are negligible [32••]. Additionally, while use of contrast media is greater with OCT guidance, previous studies have demonstrated no increased risk for contrast-induced nephropathy [47•]. In some cases, IVUS-guided stent implantation can be completed without the use of contrast in patients with end-stage renal failure [65, 66]

Currently, the ACCF/AHA/SCAI guidelines only give the use of IVUS for guidance of coronary stent implantation a class IIb ("may be considered") recommendation (Table 6). Moreover, there is no consensus statement on the role for OCT in routine clinical decision making [67]. The above findings should encourage operators to use IVI more often while the cardiology community awaits updated guideline recommendations for IVI.

Notably, the optimal criteria for IVUS-guided DES implantation have been slightly different in previous studies [19–23, 39••]. Patients who met all three criteria for IVUS guidance in the

Table 6 ACCF/AHA/SCAI guidelines for PCI recommendations (2011). [67]

Intravascular ultrasound	Optical coherence tomography
• IVUS is reasonable for the assessment of angiographically indeterminate left main coronary artery disease (Class IIa, LOE: B) • IVUS and coronary angiography are reasonable 4–6 weeks and 1 year after cardiac transplantation to exclude donor coronary artery disease, detect rapidly progressive cardiac allograft vasculopathy, and provide prognostic information (Class IIa, LOE: B) • IVUS is reasonable to determine the mechanism of stent restenosis (Class IIa, LOE: C) • IVUS may be reasonable for the assessment of non-left main coronary arteries with angiographically intermediate coronary stenosis (50–705 diameter stenosis) (Class IIb, LOE: B) • IVUS may be considered for the guidance of coronary stent implantation, particularly in cases of left main coronary artery stenting (Class IIb, LOE: B) • IVUS may be reasonable to determine the mechanism of stent thrombosis (Class IIb, LOE: C) • IVUS for routine lesion assessment is not recommended when revascularization with PCI or CABG is not being completed (Class III, LOE: C)	• The appropriate role for OCT in routine clinical decision making has not been established

CABG coronary artery bypass graft, *IVUS* intravascular ultrasound, *LOE* level of evidence, *OCT* optical coherence tomography, *PCI* percutaneous coronary intervention

ULTIMATE trial had a lower risk of 12-month TVF compared to patients with a suboptimal procedure by their IVUS criteria ($p = 0.03$) and a subgroup analysis by Gao et al. showed patients who met optimal criteria had a lower MACE rate than those undergoing an IVUS-defined suboptimal procedure [39••] [43]. Similarly, CLI-OPCI II concluded that patients who had suboptimal stent deployment by OCT had higher rates of MACE [54].

Additional investigations should focus on how procedural strategies are changed by IVI guidance. Yet, simply defining an optimal procedure is not enough. In IVUS-XPL, IVUS-guided procedures that met the optimization endpoint had a 1-year MACE rate of 1.5%; however, only one-half of subjects met this endpoint indicating that there is still room for improvement among operators [20].

Further evaluation of the impact of OCT-guided PCI on clinical outcomes is underway. For a better understanding of how OCT-guided PCI results improve clinical outcomes compared to angiographic guidance alone, the ongoing large multicenter ILUMIEN IV trial will determine the clinical implications of OCT with a primary clinical outcome of TVF [68•].

Conclusion

These findings support a favorable role for use of IVI in routine clinical practice. IVUS-guided PCI has beneficial effects on cardiovascular and all-cause mortality, ST, TLR/TVR, and MACE when compared to conventional angiography with likely neutral effects on MI. Meanwhile, OCT-guided PCI may be non-inferior to IVUS for many of the above outcomes; however, more studies are needed investigating the comparative effectiveness of these two IVI modalities head-to-head. IVUS and OCT have overlapping and complementary roles; both are superior to angiography alone, and neither should be considered superior to the other.

Compliance with Ethical Standards

Conflict of Interest Dr. Simon has nothing to disclose. Dr. Rodriguez Ziccardi has nothing to disclose. Ms. Dickens has nothing to disclose. Dr. Young has nothing to disclose. Dr. Shroff has nothing to disclose with relation to this manuscript.

Human and Animal Rights This article does not contain any studies with human or animal subjects performed by any of the authors.

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