# Improving PCI Outcomes Using Intracoronary Imaging

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# Disclosures

• None

# Background

Intravascular Ultrasound (IVUS)	Optical Coherence Tomography (OCT)
Image courtesy: Nissen S, et al. IVUS. Circ 2001.	RADIAL CROSS-SECTIONAL VIEW         Guidewire         SHADOW -         "METEOR"         LUMEN         CLEARED         OF BLOOD         VESSEL WALL

	IVUS	ОСТ	
Energy	Ultrasound	Near infrared light	
Resolution, µm	40-200 (axial), 200-300 (lateral)	15-20 (axial); 20-40 (lateral)	
Max scan diameter, mm	15	7	
Tissue penetration, mm	10	1-2.5	
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### Case-1

- 62F, remote mid-LAD PCI presented with anterior STEMI & underwent angiography guided PCI.
- Lesion prep: 2.5\*12 mm semi-compliant balloon
- Stent: 2.75\*15 mm Resolute Onyx DES





### Case-1

- Presents to ER 1 week later with crushing chest pain and anterior STE.
  - Lesion prep: 2.5\*12 mm semi compliant balloon -> Thrombectomy -> IVUS -> Post dilation using 3.0 mm NC







COR	LOE	Recommendations
2a	B-R	<ol> <li>In patients undergoing coronary stent implan- tation, IVUS can be useful for procedural guidance, particularly in cases of left main or complex coronary artery stenting, to reduce ischemic events.<sup>1-10</sup></li> </ol>
2a	B-R	<ol> <li>In patients undergoing coronary stent implan- tation, OCT is a reasonable alternative to IVUS for procedural guidance, except in ostial left main disease.<sup>11-13</sup></li> </ol>
2a	C-LD	<ol> <li>In patients with stent failure, IVUS or OCT is reasonable to determine the mechanism of stent failure.<sup>14-17</sup></li> </ol>

Lawton et al. 2021 ACC/AHA/SCAI Guideline for coronary artery revascularization



#### Figure 1.

Trend in uptake of intracoronary imaging for guiding percutaneous coronary intervention, across the United States, from 2016 to 2020. IVUS, intravascular ultrasound; OCT, optical coherence tomography.

Malik et al. Hospital-Level Variability in Use of Intracoronary Imaging for Percutaneous Coronary Intervention in the United States. JSCAI, May 2023.

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### What's the data?

#### • IVUS vs angiography

►IVUS-XPL

#### • OCT vs angiography ≻ILUMIEN IV

► ULTIMATE

**RENOVATE-PCI** 

➢OCTOBER

# What's the data? IVUS vs angiography

Study	Year	n	Follow up (months)	Bottom line
IVUS-XPL	2015	1400	12	<ul> <li>IVUS guided PCI group had lower MACE compared to angiography guided PCI</li> <li>Driven by lower ischemia driven TLR</li> </ul>
ULTIMATE	2018	1448	12	<ul><li>IVUS guided PCI group had TVF compared to angiography guided PCI</li><li>Driven by lower TVR</li></ul>
CTO-IVUS	2015	402	12	

#### **Original Investigation**

### Effect of Intravascular Ultrasound-Guided vs Angiography-Guided Everolimus-Eluting Stent Implantation The IVUS-XPL Randomized Clinical Trial

Sung-Jin Hong, MD; Byeong-Keuk Kim, MD; Dong-Ho Shin, MD, MPH; Chung-Mo Nam, PhD; Jung-Sun Kim, MD; Young-Guk Ko, MD; Donghoon Choi, MD; Tae-Soo Kang, MD; Woong-Chol Kang, MD; Ae-Young Her, MD; Yong Hoon Kim, MD; Seung-Ho Hur, MD; Bum-Kee Hong, MD; Hyuckmoon Kwon, MD; Yangsoo Jang, MD; Myeong-Ki Hong, MD, PhD; for the IVUS-XPL Investigators

#### JAMA, 2015 JACC, 2020: 5-year data

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# **IVUS-XPL**

#### • <u>Hypothesis:</u>

Long-term clinical outcomes of patients undergoing IVUS-guided PCI superior to angiography-guided PCI for long coronary lesions

• Randomized, non-blinded, multi-center study in Korea

#### • Inclusion:

>Myocardial ischemia requiring estimated >=28 mm stent length

# IVUS-XPL: JAMA, 2015

• 1:1 randomization

#### Angiography group:

Stent dimensions by visual estimation
Post dilation for residual stenosis > 30%

#### • IVUS group:

►IVUS mandatory post PCI

➢Goal: Stent minimum lumen CSA > distal reference (achieved by 54%)

	IVUS-Guided PCI	Angiography-Guided PCI	P Value
No. of patients with lesions	700	700	
Coronary arteries, No. (%)			
Left anterior descending artery	455 (65)	419 (60)	
Left circumflex artery	96 (14)	108 (15)	.14
Right coronary artery	149 (21)	173 (25)	
Baseline quantitative coronary angiographic data, mean (SD)			
Reference vessel diameter, mm	2.89 (0.45)	2.85 (0.45)	.13
Minimum lumen diameter, mm	0.83 (0.42)	0.82 (0.43)	.56
Diameter stenosis, %	71.1 (14.3)	71.4 (14.4)	.70
Lesion length, mm	34.7 (10.8)	35.2 (10.5)	.41
Adjunct postdilatation, No. (%)	534 (76)	402 (57)	<.001
Final balloon size, mean (SD), mm	3.14 (0.43)	3.04 (0.42)	<.001
Overlapping stent, No. (%)	145 (21)	138 (20)	.64
No. of stents per lesion, mean (SD)	1.3 (0.5)	1.3 (0.5)	.48
Stent edge dissections, No. (%)	15 (2)	13 (2)	.70
Coronary perforation, No. (%)	0	0	
Maximal inflation pressure, mean (SD), atm	16.5 (4.1)	15.9 (4.1)	.05
Postintervention quantitative coronary angiographi data, mean (SD)	c		
Total stented length, mm	39.3 (13.1)	39.2 (12.3)	.90
Reference vessel diameter, mm	3.03 (0.44)	2.97 (0.43)	.01
Minimum lumen diameter, mm	2.64 (0.42)	2.56 (0.39)	<.001
Diameter stenosis, %	12.79 (8.66)	13.74 (8.05)	.04

# IVUS-XPL: JAMA, 2015

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## IVUS-XPL: JAMA, 2015

#### Table 4. Clinical Outcomes at 1 Year

	IVUS-Guided PCI (n = 700) <sup>a</sup>	Angiography-Guided PCI (n = 700) <sup>a</sup>	Risk Difference (95% CI)	Hazard Ratio (95% CI) <sup>b</sup>	P Value <sup>c</sup>
Primary End Point					
Major adverse cardiac event <sup>d</sup>	19 (2.9)	39 (5.8)	-2.97 (-5.14 to -0.79)	0.48 (0.28 to 0.83)	.007
Secondary End Point					
Cardiac death	3 (0.4)	5 (0.7)	-0.30 (-1.11 to 0.52)	0.60 (0.14 to 2.52)	.48
Target lesion-related myocardial infarction	0	1 (0.1)	-0.15 (-0.45 to 0.14)		.32
Ischemia-driven target lesion revascularization	17 (2.5)	33 (5.0)	-2.39 (-4.43 to -0.36)	0.51 (0.28 to 0.91)	.02
Definite or probable stent thrombosis	2 (0.3)	2 (0.3)	0 (-0.57 to 0.56)	1.00 (0.14 to 7.10)	>.99
Acute	1 (0.1)	1 (0.1)			
Subacute	1 (0.1)	0			
Late	0	1 (0.1)			

Abbreviations: IVUS, intravascular ultrasound; PCI, percutaneous coronary intervention.

<sup>a</sup> Data are expressed as No. of patients (cumulative 1-year Kaplan-Meier event

<sup>c</sup> Calculated using the log-rank test.

<sup>d</sup> Included cardiac death, target lesion-related myocardial infarction, or ischemia-driven target lesion revascularization at 1 year.

rate percentage). <sup>b</sup> Derived from Cox proportional hazard regression models.

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## IVUS-XPL: JAMA, 2015





# Intravascular Ultrasound Versus Angiography-Guided Drug-Eluting Stent Implantation



#### The ULTIMATE Trial

Junjie Zhang, MD, PuD,<sup>a</sup>.<sup>a</sup> Xiaofei Gao, MD,<sup>a</sup>.<sup>a</sup> Jing Kan, MBBS,<sup>a</sup>.<sup>a</sup> Zhen Ge, MD,<sup>a</sup> Leng Han, MD,<sup>b</sup> Shu Lu, MD,<sup>c</sup> Nailiang Tian, MD,<sup>a</sup> Song Lin, MD,<sup>a</sup> Qinghua Lu, MD,<sup>d</sup> Xueming Wu, MD,<sup>e</sup> Qihua Li, MD,<sup>f</sup> Zhizhong Liu, PuD,<sup>a</sup> Yan Chen, MD,<sup>a</sup> Xuesong Qian, MD,<sup>b</sup> Juan Wang, MD,<sup>b</sup> Dayang Chai, MD,<sup>c</sup> Chonghao Chen, MD,<sup>e</sup> Xiaolong Li, MD,<sup>f</sup> Bill D. Gogas, MD,<sup>i</sup> Tao Pan, MBBS,<sup>a</sup> Shoujie Shan, MD,<sup>a</sup> Fei Ye, MD,<sup>a</sup> Shao-Liang Chen, MD, PuD<sup>a</sup>

#### JACC, 2018 JACC, 2021 – 3 year data

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# ULTIMATE

### • Objective:

Compare efficacy and safety between IVUS-guided and angiography-guided second-generation DES implantation in all-comers

• Randomized, multi-center (8) study

#### • Inclusion:

All comer PCI (although MI > 24 hrs from chest pain onset to admission)
 Not CTO and not requiring atherectomy

## ULTIMATE

#### • 1:1 randomization

#### Angiography group:

Stent : vessel diameter - 1.1 : 1.0 by visual estimation
 1:1 post dilation at >18 atm
 Success: TIMI 3, stenosis < 20%, absence of >=type B dissection

#### • IVUS group:

Reference segment: <40% plaque burden</p>

Landing zones: <50% plaque burden</p>

Stent sizing: 0.8:1 for sizing using media or 1:1 using lumen

- 1:1 post dilation at >18 atm
- Optimum result: (achieved by 53%)
  - $\checkmark$  MLA > 5 mm<sup>2</sup> OR 90% MLA at distal reference
  - ✓ Plaque burden within 5 mm of stent edges < 50%
  - ✓ No edge dissection involving media >=3mm

<b>TABLE 2</b> Angiographic and Procedural Characteristics of Treated Lesions				
	IVUS Guidance	Angiography Guidance	p Value	
Total number of lesions treated	962	1,016		
Mean lesion length, mm	$35.06 \pm 21.68$	34.05 ± 20.70	0.29	
Lesion specificities			0.51	
Left main trunk	95 (9.9)	87 (8.6)		
Left anterior descending artery	457 (47.5)	474 (46.7)		
Left circumflex artery	166 (17.3)	171 (16.8)		
Right coronary artery	244 (25.4)	284 (28.0)		
Multi-vessel disease*	381 (52.6)*	414 (57.2)*	0.08	
AHA/ACC lesion type B2/C	636 (66.1)	688 (67.7)	0.45	
Bifurcation lesion	226 (23.5)	269 (26.5)	0.13	
2-stent technique	84 (8.7)	98 (9.6)	0.48	
Chronic total occlusion	85 (8.8)	91 (9.0)	0.93	
Moderate to several calcification lesions	243 (25.3)	246 (24.2)	0.59	
Radial access*	686 (94.8)	701 (96.8)	0.07	
Post-dilation performed	928 (96.6)	956 (94.9)	0.11	

Per patient*			
Stent number	$2.40 \pm 1.55$	$2.47 \pm 1.56$	0.39
Mean stent diameter, mm	$3.15 \pm 0.42$	$2.99 \pm 0.38$	< 0.001
Mean stent length, mm	66.42 ± 46.17	66.49 ± 44.36	0.98
Maximum balloon diameter, mm	$3.84 \pm 0.52$	$3.62 \pm 0.51$	< 0.001
Maximum post-dilation pressure, atm	$19.8 \pm 3.7$	$19.2 \pm 3.6$	0.003
Per lesion			
Stent number	$\textbf{1.81} \pm \textbf{0.80}$	$1.76 \pm 0.77$	0.16
Mean stent diameter, mm	$3.14 \pm 0.51$	$2.97 \pm 0.48$	<0.001
Mean stent length, mm	49.99 ± 25.10	47.38 ± 22.42	0.02
Maximum balloon diameter, mm	$3.73 \pm 0.56$	$3.51 \pm 0.53$	<0.001
Maximum post-dilation pressure, atm	$19.7 \pm 3.7$	$19.0 \pm 3.7$	<0.001
Total stent numbers	1,738	1,788	0.10
Everolimus-eluting stent	235 (13.5)	257 (14.4)	
Zotarolimus-eluting stent	593 (34.1)	549 (30.7)	
Sirolimus-eluting stent	910 (52.4)	982 (54.9)	
Complete revascularization*	531 (73.3)*	543 (75.0)*	0.47
Angiographic success	943 (98.0)	994 (97.8)	0.77
Procedural time, min*	60.88 ± 28.41	$45.49 \pm 26.43$	< 0.001
Contrast volume, ml*	$178.29 \pm 64.08$	161.96 ± 55.44	<0.001
CIN*	57 (7.9)*	42 (5.8)*	0.12

TABLE 3 Intention-to-Treat Clinical Outcomes From Patient-Level Analysis						
	IVUS Guidance (n = 724)	Angiography Guidance (n = 724)	Hazard Ratio (95% Cl)	p Value		
At 30-day follow-up						
Target-vessel failure	6 (0.8)	14 (1.9)	0.427 (0.164-1.111)	0.08		
Cardiac death	1 (0.1)	3 (0.4)	0.332 (0.035-3.195)	0.32		
Target-vessel MI	5 (0.7)	11 (1.5)	0.454 (0.158-1.305)	0.14		
Periprocedural MI	5 (0.7)	9 (1.2)	0.555 (0.186-1.656)	0.28		
Spontaneous MI	0 (0.0)	2 (0.3)	-	0.16		
Clinically driven TVR	0 (0.0)	2 (0.3)	-	0.16		
Clinically driven TLR	0 (0.0)	2 (0.3)	-	0.16		
CABG	0 (0.0)	0 (0.0)	-	NS		
Target-lesion failure	6 (0.8)	14 (1.9)	0.427 (0.164-1.111)	0.08		
All-cause death	1 (0.1)	5 (0.7)	0.199 (0.023-1.707)	0.10		
Definite or probable ST	1 (0.1)	5 (0.7)	0.199 (0.023-1.704)	0.10		
Stroke	1 (0.1)	2 (0.3)	0.499 (0.045-5.499)	0.56		
At 1-yr follow-up						
Target-vessel failure	21 (2.9)	39 (5.4)	0.530 (0.312-0.901)	0.02		
Cardiac death	5 (0.7)	10 (1.4)	0.497 (0.170-1.453)	0.19		
Target-vessel MI	7 (1.0)	11 (1.5)	0.634 (0.246-1.636)	0.34		
Spontaneous MI	3 (0.4)	2 (0.3)	1.490 (0.249-8.917)	0.66		
Clinically driven TVR	11 (1.5)	21 (2.9)	0.514 (0.248-1.066)	0.07		
Clinically driven TLR	9 (1.2)	19 (2.6)	0.466 (0.211-1.030)	0.05		
CABG	0 (0.0)	2 (0.3)	-	0.16		
Target-lesion failure	20 (2.8)	37 (5.1)	0.533 (0.309-0.918)	0.02		
Clinically driven TLR or definite ST	9 (1.2)	19 (2.6)	0.466 (0.211-1.030)	0.05		
All cause death	10 (1.4)	17 (2.3)	0.584 (0.267-1.275)	0.17		
Definite or probable ST	1 (0.1)	5 (0.7)	0.199 (0.023-1.704)	0.10		
Definite ST	0 (0.0)	2 (0.3)	-	0.16		
Probable ST	1 (0.1)	3 (0.4)	0.332 (0.034-3.188)	0.32		
Stroke	5 (0.7)	4 (0.6)	1.241 (0.333-4.620)	0.75		



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# ULTIMATE: 3 year follow-up



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#### ORIGINAL ARTICLE

## Intravascular Imaging–Guided or Angiography-Guided Complex PCI

J.M. Lee, K.H. Choi, Y.B. Song, J.-Y. Lee, S.-J. Lee, S.Y. Lee, S.M. Kim, K.H. Yun, J.Y. Cho, C.J. Kim, H.-S. Ahn, C.-W. Nam, H.-J. Yoon, Y.H. Park, W.S. Lee, J.-O. Jeong, P.S. Song, J.-H. Doh, S.-H. Jo, C.-H. Yoon, M.G. Kang, J.-S. Koh, K.Y. Lee, Y.-H. Lim, Y.-H. Cho, J.-M. Cho, W.J. Jang, K.-J. Chun, D. Hong, T.K. Park, J.H. Yang, S.-H. Choi, H.-C. Gwon, and J.-Y. Hahn, for the RENOVATE-COMPLEX-PCI Investigators\*

#### NEJM, 2023

# **RENOVATE-COMPLEX PCI**

#### • **Objective:**

Does intravascular imaging—guided PCI (IVUS or OCT) improve clinical outcomes vs. angiography-guided complex PCI?

• Multicenter, randomized, open label (2:1)

#### • Inclusion:

> Bifurcation lesions
 > CTO
 > Unprotected LM
 > long lesions (stent length >= 38 mm)
 > Multi-vessel PCI

- >At least 3 stents needed
- ►ISR
- Severely calcified lesion
- ➤Ostial lesions

# **RENOVATE-COMPLEX PCI**

#### • IVI group:

- > IVUS / OCT per operator preference
- Mandatory post stent
- > Optimum result:
  - Residual lesion <10%</p>
  - MSA >80% of mean ref, lumen area OR
  - IVUS MSA >5.5 mm2 / OCT MSA >4.5 mm2 in non-LM
  - LM: MSA >7 mm2 for distal and >8 mm2 for proximal
  - No major stent malapposition, or edge dissection

![](_page_26_Figure_0.jpeg)

### IVUS guided PCI provides mortality benefit

#### Figure 4b, Forest plot for cardiovascular mortality

![](_page_27_Figure_2.jpeg)

Malik A, et al. Intravascular ultrasound-guided stent implantation reduces cardiovascular mortality - Updated meta-analysis of randomized controlled trials. Int J Cardiol, 2020.

9/7/2023

### IVUS guided PCI provides mortality benefit

![](_page_28_Figure_1.jpeg)

• Propensity matched patients from New York PCI registry who underwent PCI of complex lesions

Hannan E, et al. Percutaneous Coronary Intervention With and Without Intravascular Ultrasound for Patients With Complex Lesions. Circ CV Int 2022.

# Optical Coherence Tomography–Guided versus Angiography-Guided PCI

Ziad A. Ali, M.D., D.Phil., Ulf Landmesser, M.D., Akiko Maehara, M.D., Mitsuaki Matsumura, B.S., Richard A. Shlofmitz, M.D., Giulio Guagliumi, M.D., Matthew J. Price, M.D., Jonathan M. Hill, M.D., Takashi Akasaka, M.D., Francesco Prati, M.D., Hiram G. Bezerra, M.D., William Wijns, M.D., Ph.D., David Leistner, M.D., Paolo Canova, M.D., Fernando Alfonso, M.D., Franco Fabbiocchi, M.D., Ozgen Dogan, M.D., Robert J. McGreevy, Ph.D., Robert W. McNutt, Ph.D., Hong Nie, Ph.D., Jana Buccola, M.S., Nick E.J. West, M.D., and Gregg W. Stone, M.D., for the ILUMIEN IV Investigators\*

### • Objective:

Safety and effectiveness of OCT-guided PCI in high-risk patients and lesions

• Single blind, multi-center RCT (1:1)

### • Inclusion:

- ▶ Ischemia needing PCI with 2.5-3.5 mm stents, left main excluded
- ≻High risk: DM on Rx
- High risk lesion: causing MI, >28 mm stent, bifurcation, severely calcified, CTO, diffuse/multifocal ISR

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• <u>Angiography group</u>: Standard PCI procedures per local practice

#### • OCT group:

<u>Pre stent OCT</u>: best lesion prep, morphology, length, diameter

Stent sizing:

Distal reference EEL rounded down to nearest size OR

> Distal reference mean lumen rounded up to nearest size

#### Post stent OCT

> MSA at least 90% in proximal and distal segments relative to closest reference segment

 $\blacktriangleright$  MLA  $\geq$ 4.5 mm2, 5 mm from stent edges

 $\succ$  Additional DES if major dissection ( $\geq$ 60° circumference,  $\geq$ 3 mm length)

![](_page_32_Figure_1.jpeg)

Variable	OCT Guidance (N = 1233)	Angiography Guidance (N=1254)	Hazard Ratio or Difference (95% CI)	P Value
Stent thrombosis — no. (%)				
Definite or probable	6 (0.5)	17 (1.4)	0.36 (0.14 to 0.91)‡	0.02
Acute, <24 hr	2 (0.2)	4 (0.3)	0.51 (0.09 to 2.78)‡	
Subacute, 24 hr to 30 days	3 (0.2)	5 (0.4)	0.61 (0.15 to 2.55)‡	
Late, >30 days to 1 yr	1 (0.1)	6 (0.5)	0.17 (0.02 to 1.39)‡	
Very late, >1 yr to 2 yr	0	2 (0.2)	_	
Definite	5 (0.4)	14 (1.1)	0.36 (0.13 to 1.00)‡	
Probable	2 (0.2)	3 (0.2)	0.68 (0.11 to 4.04)‡	

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# OCT or Angiography Guidance for PCI in Complex Bifurcation Lesions

N.R. Holm, L.N. Andreasen, O. Neghabat, P. Laanmets, I. Kumsars, J. Bennett, N.T. Olsen, J. Odenstedt, P. Hoffmann, J. Dens, S. Chowdhary, P. O'Kane,
S.-H. Bülow Rasmussen, M. Heigert, O. Havndrup, J.P. Van Kuijk, S. Biscaglia,
L.J.H. Mogensen, L. Henareh, F. Burzotta, C. H. Eek, D. Mylotte, M.S. Llinas,
L. Koltowski, P. Knaapen, S. Calic, N. Witt, I. Santos-Pardo, S. Watkins,
J. Lønborg, A.T. Kristensen, L.O. Jensen, F. Calais, J. Cockburn, A. McNeice,
O.A. Kajander, T. Heestermans, S. Kische, A. Eftekhari, J.C. Spratt,
and E.H. Christiansen, for the OCTOBER Trial Group\*

## OCTOBER trial – NEJM 2023

#### • **Objective:**

Is PCI with OCT guidance superior to angiography-guided PCI in complex bifurcation lesions?

• Multicenter, open label, RCT (1:1)

#### • Inclusion:

Stable / unstable angina, NSTEMI

MB ref. diameter >= 2.75 mm, visual stenosis >= 50%

SB ref. diameter >= 2.5 mm, stenosis >= 50% within 5 mm of ostium

LM included (IVUS allowed in angiography group, used in 15%)

## OCTOBER trial – NEJM 2023

#### OCT group goals:

Optimal lesion coverage: 5-mm edge zones <= 30% stenosis, no major lipid plaque or plaque rupture, no angiographic edge dissection</p>

#### > Optimal stent expansion:

- Residual stenosis < 10%</p>
- If provisional stenting, < 50% SB stenosis</p>

>No malapposition: Entire stent in contact with vessel wall

#### > No crushed or distorted stents: Visual confirmation

Table 2. Procedural Characteristics.*					
Characteristic	Total (N = 1201)	OCT-Guided PCI (N = 600)	Angiography- Guided PCI (N=601)		
Median no. of diseased vessels (IQR)	2 (2-2)	2 (2-2)	2 (2-2)		
Median no. of lesions to be treated (IQR)	1 (1-1)	1 (1-1)	1 (1-1)		
Trial bifurcation vessels — no. of patients (%)					
LMCA–LAD–LCx	227 (18.9)	111 (18.5)	116 (19.3)		
LAD-D	847 (70.5)	425 (70.8)	422 (70.2)		
LCx–OM	111 (9.2)	55 (9.2)	56 (9.3)		
RCA–PDA–PLA	16 (1.3)	9 (1.5)	7 (1.2)		
Main-vessel treatment, median total stent length (IQR) — mm	36 (24–50)	38 (28–51)	33 (23–48)		
Side-branch treatment					
Side branch stented — no. of patients/total no. (%)	770/1198 (64.3)	388/597 (65.0)	382/601 (63.6)		
Median total stent length (IQR) — mm	23 (15-28)	23 (15-28)	23 (15–28)		
Median total balloons (IQR) — no.	7 (5–9)	7 (5–10)	6 (5–9)		
Largest balloon diameter — mm	4.1±0.02	4.2±0.03	4.0±0.02		
Secondary lesions treated — no. of patients (%)	231 (19.2)	106 (17.7)	125 (20.8)		

![](_page_38_Figure_0.jpeg)

![](_page_39_Figure_0.jpeg)

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