Potential conflicts of interest

Speaker's name: Takashi Akasaka

❑   **I do not have any potential conflict of interest**

☑   **I have the following potential conflicts of interest to report:**

Honorarium: None

Institutional grant/research support: *Terumo Cooperation*

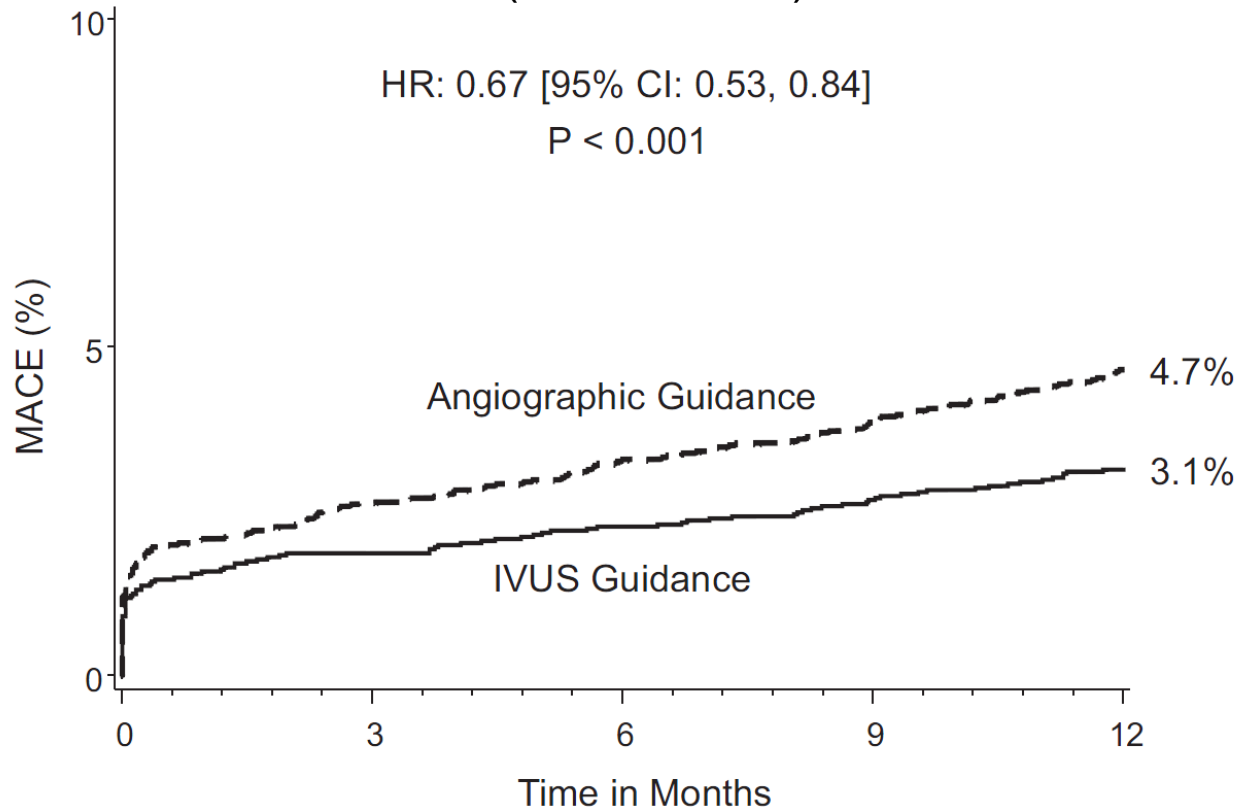Consultant: *Terumo Cooperation*

Employment in industry: None

Owner of a healthcare company: None

Stockholder of a healthcare company: None

Other(s): *This study was sponsored by Terumo Cooperation*
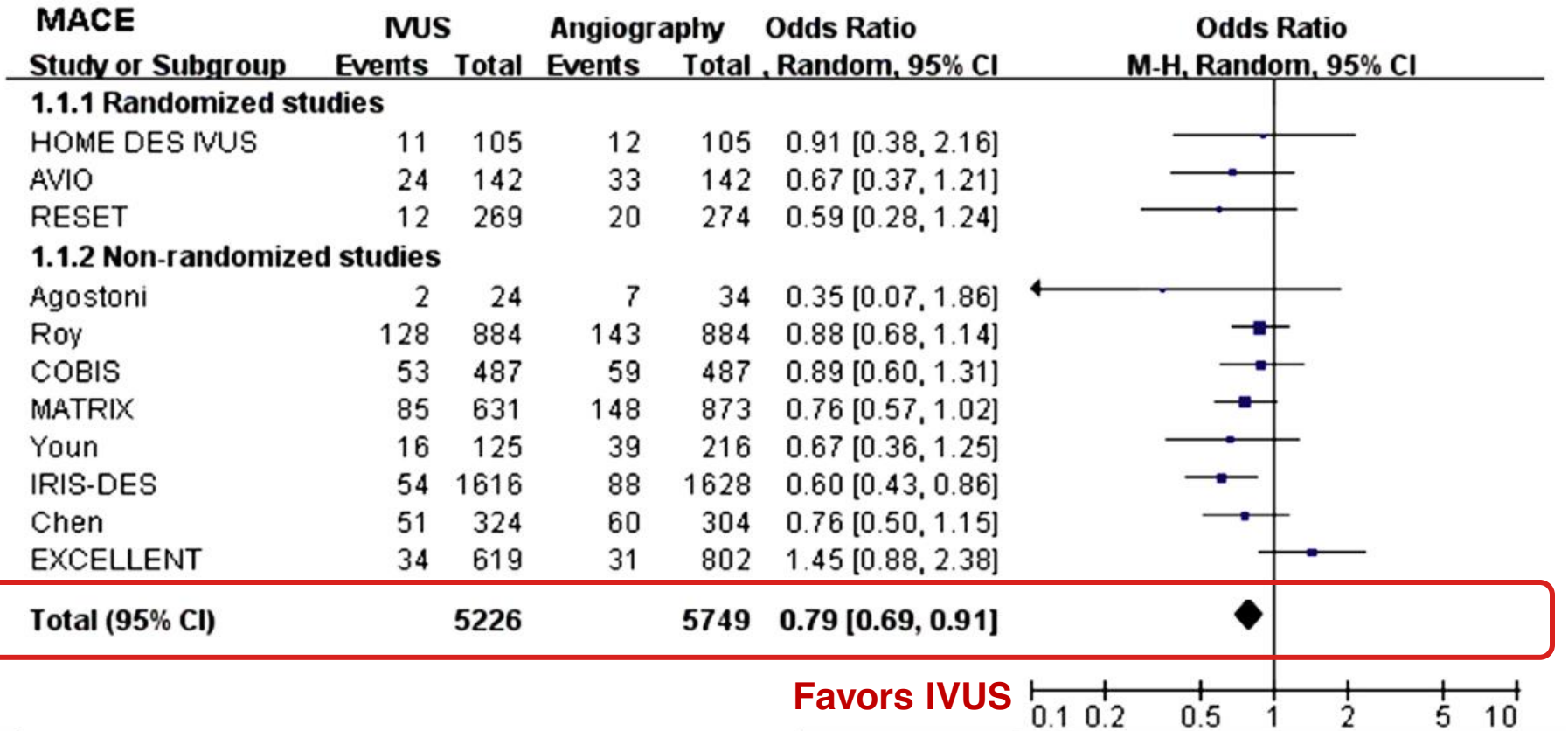
IVUS- vs. angio-guided PCI with DES

Results from Assessment of Dual Antiplatelet Therapy With Drug-Eluting Stents (ADAPT-DES)

IVUS guidance was associated with a reduction in stent thrombosis, MI, and MACE within 1 year after DES implantation.

Witzenbichler, et al., Circulation. 2014;129:463-470

IVUS- vs. angio-guided PCI with DES

A meta-analysis of randomized trials and observational studies

MACE Study or Subgroup	IVUS Events	Total	Angiography Events	Total	Odds Ratio Random, 95% CI	Odds Ratio M-H, Random, 95% CI
1.1.1 Randomized studies						
HOME DES IVUS	11	105	12	105	0.91 [0.38, 2.16]	
AVIO	24	142	33	142	0.67 [0.37, 1.21]	
RESET	12	269	20	274	0.59 [0.28, 1.24]	
1.1.2 Non-randomized studies						
Agostoni	2	24	7	34	0.35 [0.07, 1.86]	
Roy	128	884	143	884	0.88 [0.68, 1.14]	
COBIS	53	487	59	487	0.89 [0.60, 1.31]	
MATRIX	85	631	148	873	0.76 [0.57, 1.02]	
Youn	16	125	39	216	0.67 [0.36, 1.25]	
IRIS-DES	54	1616	88	1628	0.60 [0.43, 0.86]	
Chen	51	324	60	304	0.76 [0.50, 1.15]	
EXCELLENT	34	619	31	802	1.45 [0.88, 2.38]	
Total (95% CI)		5226		5749	**0.79 [0.69, 0.91]**	

Favors IVUS   0.1 0.2   0.5   1   2   5   10

IVUS-guided DES implantation is associated with significantly lower rates of adverse clinical events compared with angiography guidance.

OCT- vs. angio-guided PCI with DES or BMS

The retrospective Centro per la Lotta contro l'Infarto-Optimisation of Percutaneous Coronary Intervention (CLI-OPCI) study

Events at 1-year follow-up	Angiographic guidance group (n=335)	Angiographic plus OCT guidance group (n=335)	*p*-value
Death	23 (6.9%)	11 (3.3%)	0.035
Cardiac death	15 (4.5%)	4 (1.2%)	0.010
Myocardial infarction	29 (8.7%)	18 (5.4%)	0.096
Target lesion repeat revascularisation	11 (3.3%)	11 (3.3%)	1.0
Definite stent thrombosis	2 (0.6%)	1 (0.3%)	1.0
Cardiac death or myocardial infarction	43 (13.0%)	22 (6.6%)	0.006
Cardiac death, myocardial infarction, or repeat revascularisation	50 (15.1%)	32 (9.6%)	0.034

The use of OCT can improve clinical outcomes of patients undergoing PCI.

IVUS/OCT in ESC guideline 2014

Recommendations	Class	Level
IVUS in selected patients to optimize stent implantation.	IIa	B
OCT in selected patients to optimize stent implantation.	IIb	C

Eur Heart J. 2014;35:2541-2619

- The resolution of OCT is 10 times higher than that of IVUS.
- OCT is capable of providing accurate coronary measurements.
- OCT is more accurate than IVUS in detecting subtle stent morphologies including malapposition, residual thrombus, plaque prolapse, and residual dissections.
- Further studies are needed to define the clinical value of OCT.

Objective

We designed the OPINION trial powered to evaluate the non-inferiority of OFDI-guided PCI compared with IVUS-guided PCI in terms of clinical outcomes.

The OPINION study design

Prospective, multi-center (n=42), randomized (1:1) non-inferiority trial
comparing OFDI-guided PCI with IVUS-guided PCI

Patients scheduled for PCI using DES
n = 800

OFDI-guided PCI
n = 400

Randomization
1:1

IVUS-guided PCI
n = 400

Follow up coronary angiography
8 months

Clinical follow up
12 months

PI: Takashi Akasaka, MD,PhD, FESC
Sponsor: Terumo corporation

Patient population

Inclusion criteria

Patients scheduled for PCI using DES to a de novo native coronary artery lesion

Exclusion criteria

STEMI or NSTEMI in previous 3 months
Cardiogenic shock
Congestive heart failure
Chronic kidney disease (eGFR < 30 ml/min/1.73 m^2 or serum creatinine >1.5mg/dl)
Hemodialysis or peritoneal dialysis
Three-vessel disease
Left main coronary artery disease
Aorto-Ostial lesion arising within 3mm of the origin of a coronary artery
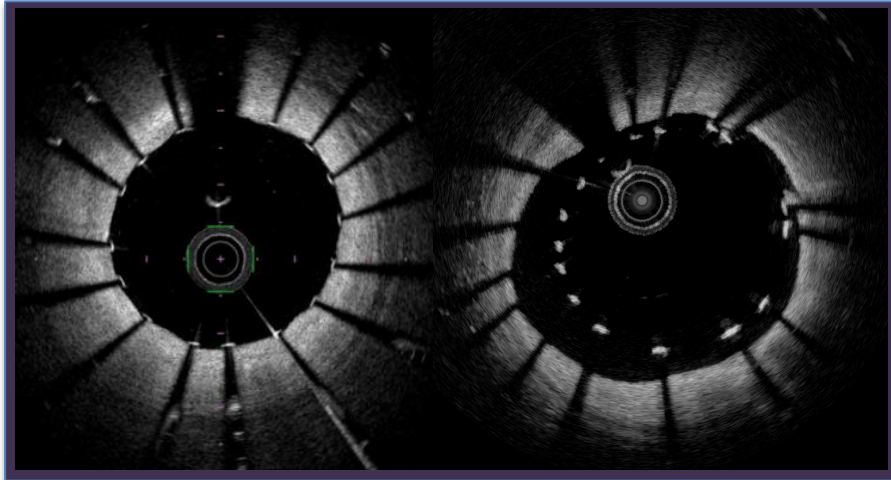Chronic total occlusion
Small vessel disease (reference vessel diameter < 2.5 mm)
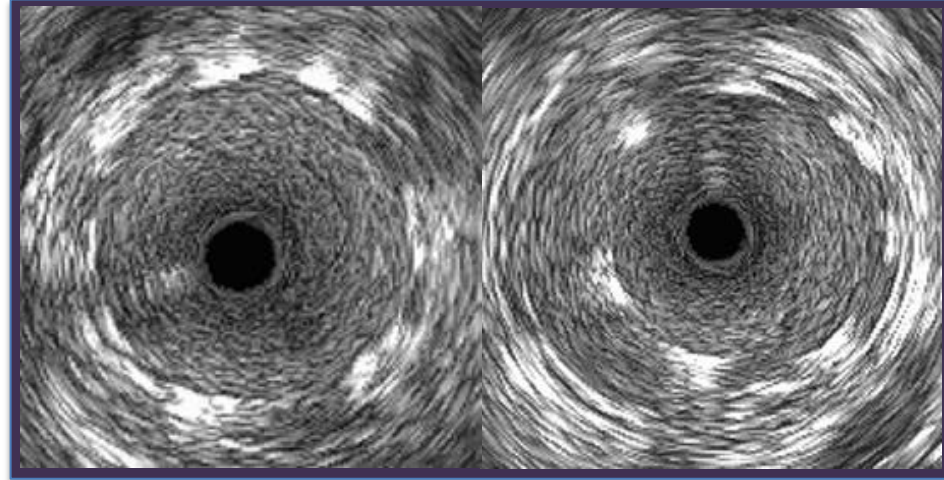
Imaging modalities and Stent

OFDI
LUNAWAVE and FastView

IVUS
VISIWAVE and ViewIT (40MHz)

DES
NOBORI, biolimus-eluting stent

OFDI and IVUS criteria of optimal stent deployment

	OFDI-guided PCI	IVUS-guided PCI
Reference site	• Most normal looking • No lipidic plaque	• Largest lumen • Plaque burden < 50%
Determination of stent diameter	• By measuring lumen diameter at proximal and distal reference sites	• By measuring vessel diameter at proximal and distal reference sites
Determination of stent length	• By measuring distance from distal to proximal reference site	
Goal of stent deployment	• In-stent minimal lumen area ≥ 90% of the average reference lumen area • Complete apposition of the stent over its entire length against the vessel wall • Symmetric stent expansion defined by minimum lumen diameter / maximum lumen diameter ≥ 0.7 • No plaque protrusion, thrombus, or edge dissection with potential to provoke flow disturbances	

Endpoints

Primary endpoint

Target Vessel Failure: TVF* at 12 months after PCI

* Composite of cardiac death, target vessel-related MI and clinically-driven TVR

Secondary endpoints

Following parameters at 12 months after PCI

- Cardiac death
- MI
- Stent thrombosis
- Binary restenosis
- Clinically-driven TLR

- Clinically-driven TVR
- MACE (Cardiac death, MI, and TLR)
- Stroke
- Contrast-induced nephropathy

Sample size calculation

- With the assumption of 9% TVF rate at 12 months after IVUS-guided PCI with BES, a total of 774 patients would yield 80% power to detect non-inferiority with a non-inferiority margin of 7% at a one-sided significance level of 0.05.

- A total of 800 patients are to be enrolled considering possible dropout during follow-up.
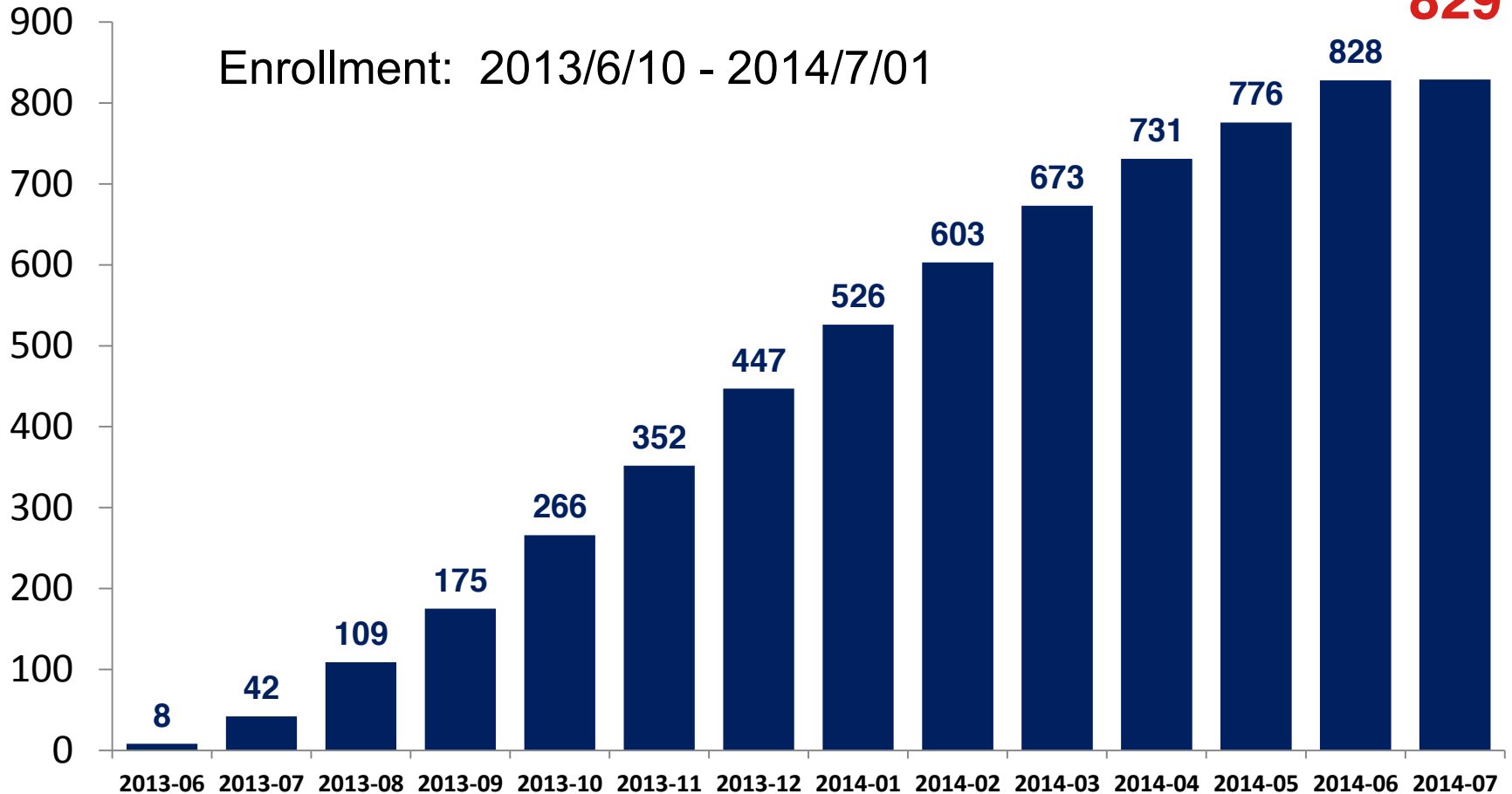
Baseline patient characteristics

	OFDI	IVUS	*p*-value
Age, yrs	68 ± 9	68 ± 9	0.431
Male	77%	79%	0.365
Hypertension	77%	74%	0.389
Dyslipidemia	76%	80%	0.279
Diabetes mellitus	41%	41%	0.917
Current smoker	16%	18%	0.396
Obesity (BMI > 25)	31%	28%	0.389
Stable AP	88%	87%	0.471
ACS	12%	13%	0.471

Interim data, as of 16 March, 2015

Angiographic findings

	OFDI	IVUS	*p*-value
LAD / LCX / RCA	54 / 20 / 26%	49 / 22 / 29%	0.422
Ostial	6%	7%	0.629
Bifurcation	38%	40%	0.595
Heavy calcification	8%	13%	0.011
Thrombus	1%	1%	0.721
Severe tortuosity	5%	4%	0.244
Reference vessel diameter	2.61 ± 0.54	2.58 ± 0.59	0.517
Minimal lumen diameter	0.93 ± 0.37	0.88 ± 0.38	0.103
% DS	64 ± 13	66 ± 13	0.104
Lesion length	17.9 ± 10.2	16.8 ± 10.2	0.226

Interim data, as of 16 March, 2015

OFDI / IVUS imaging

	OFDI	IVUS	*p*-value
No. of imaging procedure	3.1 ± 1.7	3.0 ± 1.1	0.326
Imaging at pre-stenting	98%	97%	0.324
Imaging at post-stenting	99.8%	99.5%	0.629
Total contrast volume, ml	164 ± 66	138 ± 56	< 0.001
Contrast volume for OFDI, ml	33 ± 30	-	-
Auto injection	72%	-	-
Manual injection	28%	-	-

Procedural characteristics

	OFDI	IVUS	*p*-value
Stent diameter, mm	2.93 ± 0.39	2.99 ± 0.40	0.032
Stent length, mm	22 ± 7	21 ± 7	0.248
No. of stents	1.2 ± 0.4	1.2 ± 0.4	0.500
Total stent length, mm	26 ± 13	25 ± 13	0.284
Post dilatation	78%	76%	0.593
Max. balloon diameter, mm	3.15 ± 0.79	3.28 ± 1.20	0.072
Max. inflation pressure, atm	16 ± 4	16 ± 4	0.840
PCI procedure success	99.5%	100%	0.499

Interim data, as of 16 March, 2015

QCA results immediately after PCI

	OFDI	IVUS	*p*-value
In-stent			
MLD, mm	2.56 ± 0.44	2.63 ± 0.46	0.058
DS, %	12 ± 6	11 ± 5	0.021
Acute gain, mm	1.63 ± 0.49	1.75 ± 0.50	0.003
In-segment			
MLD, mm	2.25 ± 0.52	2.28 ± 0.52	0.481
DS, %	21 ± 9	21 ± 9	0.912
Acute gain, mm	1.33 ± 0.54	1.40 ± 0.53	0.110

Interim data, as of 16 March, 2015

Peri-procedural complication

	OFDI	IVUS	*p*-value
No. of complication	37 (9.1%)	36 (9.3%)	0.956
Acute coronary occlusion	1 (0.2%)	0 (0.0%)	0.593
Air embolism	2 (0.5%)	2 (0.5%)	0.999
Slow / no flow	8 (2.0%)	9 (2.3%)	0.782
Distal embolization	2 (0.5%)	1 (0.3%)	0.999
Side branch occlusion	8 (2.0%)	7 (1.8%)	0.817
Coronary dissection	10 (2.5%)	7 (1.8%)	0.481
Thrombosis	1 (0.2%)	2 (0.5%)	0.622
Spasm	2 (0.5%)	5 (1.3%)	0.247
Arrhythmia	2 (0.5%)	1 (0.3%)	0.999
Others	1 (0.2%)	2 (0.5%)	0.622

Interim data, as of 16 March, 2015

OPINION baseline analysis conclusions

- OPINION is a trial powered to evaluate the non-inferiority of OFDI-guided PCI compared with IVUS-guided PCI in terms of late clinical outcome.

- In-segment MLD by QCA immediately after PCI was comparable between OFDI-guided PCI and IVUS-guided PCI, although the size of used stent was smaller in OFDI-guided PCI.

- Clinical follow-up is ongoing and 12 months clinical result will be shown soon.

- OPINION will define the clinical value of OCT in PCI.

Study organization

- **Principal investigator:** Takashi Akasaka, Wakayama Medical University

- **Angiographic core lab:** Ken Kozuma, CardioCore Japan

- **OFDI/IVUS core lab:** Hiromasa Otake, Kobe University

- **Statistical analysis:** Shinichiro Maruo, TRI

- **Data center:** TRI data center

- **OPINION organizer** Takashi Kubo, Wakayama Medical University

- **OPINION TRI secretariat:** Translational Research Informatics Center (TRI), Foundation for Biomedical Research and Innovation

OPINION investigational sites

Institute

- Wakayama Medical University
- Seirei Hamamatsu General Hospital
- Hyogo Brain and Heart Center
- JCHO Hokkaido Hospital
- Tokai University School of Medicine
- Iwate Medical University
- Tenyoukai Central Hospital
- Kobe University Graduate School of Medicine
- Caress Sapporo Hokko Memorial Hospital
- Urasoe General Sogo Hospital
- Yokohama City University Medical Center
- Yamaguchi University Graduate School of Medicine
- Akashi Medical Center
- Kanazawa Cardiovascular Hospital
- Okamura Memorial Hospital
- Miyazaki Medical Association Hospital
- Akita Medical Center
- Saiseikai Fukuoka General Hospital
- Nara Medical University
- Bell Land General Hospital
- Osaka Saiseikai Nakatsu Hospital

- Hyogo College of Medicine
- Osaka City University
- Cardiovascular Center, Sakakibara Hospital
- Yodogawa Christian Hospital
- Higashisumiyoshi Morimoto Hospital
- Tsuchiya General Hospital
- Aichi Medical University
- Nippon Medical School Chiba Hokusou Hospital
- Saitama Sekishinkai Hospital
- Kokura Memorial Hospital
- University of Occupational and Environmental Health
- Kitasato University
- Teikyo University School of Medicine
- Kawasaki Medical School Hospital
- Fukuoka Wajiro Hospital
- Shingu Municipal Medical Center
- Showa University Fujigaoka Hospital
- Kyoto University Graduate School of Medicine
- Mitsui Memorial Hospital
- Yokosuka City Hospital
- Tokyo Medical and Dental University Hospital