True Distal Left Main Bifurcation PCI (Medina 1,1,1, or 1,0,1):
Contemporary Strategy – Provisional vs. Complex Stenting

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Disclosure

• I have noting to disclose
Survival Benefit of Revascularization

CT-FFR: Myocardial Mass >10%
Ture Distal LM Bifurcation Lesion

Focal moderate lesion in LCX

Focal severe lesion in LCX

Diffuse lesion in LCX

“Anatomic Diversity of Distal Left Main Disease”
Anatomic Diversity of Distal LM Bifurcation PCI

The approach is usually dictated by the SB (LCX):

- True vs. Non-true
- Size of SB (LCX)
- Angle from MB (LAD)
- Extent and distribution of SB (LCX) disease
- How important the LCX (SB) is for that patient and for that specific anatomy
DKCRUSH V – DK Crush vs. Provisional Stenting in Distal LM True Bifurcations: TLF at 12-month

Hazard ratio [95%CI] = 0.46 [0.23-0.91]  
P=0.02

Chen, S.-L et al, JACC 2017; 70(21):2605-17
Better Strategy for Distal LM bifurcation? 

DKCRUSH-V Trial

Provisional 1-Stent vs. Planned 2-Stents For LM Distal Bifurcation Disease (n=529)

Site-assessed distal LM bifurcation disease with QCA
N=524

0 or 1 side branches with DS ≥50% by QCA
N=342 (65.3%)

2 side branches with DS ≥50% by QCA
N=182 (34.7%)

Provisional 1-stent
N=264

Planned 2-stent
N=78

Provisional 1-stent
N=77

Planned 2-stent
N=105
Provisional 1-Stent vs. Planned 2-Stents For LM Distal Bifurcation Disease (n=529)

Death, stroke or MI (%)

- Provisional 1-stent and 0-1 SB with DS ≥50%
- Planned 2-stents and 0-1 SB with DS ≥50%
- Provisional 1-stent and 2 SBs with DS ≥50%
- Planned 2-stents and 2 SBs with DS ≥50%

HR [95% CI = 0.56 [0.32, 0.99] P = 0.04

HR [95% CI = 0.71 [0.34, 1.48] P = 0.36

Number at risk:
- Provisional 1-stent and 0-1 SB with DS ≥50%
  - 77  73  72  69  67  67  64
  - 264 246 242 238 233 227 218

- Planned 2-stents and 0-1 SB with DS ≥50%
  - 105  90  88  86  85  83  82
  - 78   70  69  64  61  60  55

Kandzari DE et al. Submitted
Provisional 1-Stent vs. Planned 2-Stents For LM Distal Bifurcation Disease (n=529)

Provisional 1-stent and 0-1 SB with DS ≥50%
Planned 2-stents and 0-1 SB with DS ≥50%

Provisional 1-stent and 2 SBs with DS ≥50%
Planned 2-stents and 2 SBs with DS ≥50%

HR [95% CI = 0.46 [0.21, 1.01] P = 0.047

HR [95% CI = 0.90 [0.34, 2.36] P = 0.83

Number at risk:
- All-cause death (%)

Kandzari DE et al. Submitted
Real-World Data Is Still Lacking...

Left Main Bifurcation PCI:
Merged Analysis using the Largest Real-World Left Main Database
Safety and Effectiveness of Second-Generation Drug-Eluting Stents in Patients With Left Main Coronary Artery Disease

Pil Hyung Lee, MD, Osung Kwon, MD, Jung-Min Ahn, MD, Cheol Hyun Lee, MD, Do-Yoon Kang, MD, Jung-Bok Lee, PhD, Soo-In Kang, MD, PhD, Seung-Whan Lee, MD, PhD, Young-Tak Kim, MD, PhD, Cheol Whan Lee, MD, PhD, Seong-Wook Park, MD, PhD, Duk-Woo Park, MD, PhD, Seung-Jung Park, MD, PhD

ABSTRACT

BACKGROUND Limited data are available on the relative performances between different types of drug-eluting stents (DES) for obstructive left main coronary artery disease (LMCAD).

OBJECTIVES This study sought to compare effectiveness and safety profiles of various second-generation DES for LMCAD in real-world clinical practice.

METHODS Among 4,470 patients in 3, multicenter, prospective registries (IRIS-DES [Interventional Cardiology Research Incorporation Society-Drug-Eluting Stents] registry, the IRIS-MAIN [Interventional Cardiology Research Incorporation Society-Left MAIN Revascularization] registry, and the PRECOMBAT [PREmeier of Randomized COMparison of Bypass Surgery versus Angioplasty Using Drug-Eluting Stent in Patients with Left Main Coronary Artery Disease] study) treated between July 2007 and July 2015, the authors identified 2,692 patients with significant LMCAD who received second-generation DES; 1,254 with cobalt-chromium everolimus-eluting stents (Ccr-EES), 232 with biodegradable polymer biolimus-eluting stents (BP-BES), 616 with platinum-chromium EES (PtCr-EES), and 590 with Resolute Zotarolimus-eluting stent (Re-ZES). The primary outcome was target-vessel failure.

RESULTS The observed 3-year rates of target-vessel failure were not significantly different for the different types of DES (16.7% for the Ccr-EES, 13.2% for the BP-BES, 18.7% for the PtCr-EES, and 14.7% for the Re-ZES; p = 0.15). In multiple treatment propensity score analysis, the adjusted hazard ratios (HRs) for target-vessel failure were similar in between-group comparisons of the different DES, except for the PtCr-EES versus the BP-BES (reference; HR: 1.60; 95% confidence interval: 1.01 to 2.54; p = 0.046). There were no significant differences in risk of composite of all-cause death, any myocardial infarction, or any revascularization and its individual components according to the different types of DES. Although the 3-year incidence of stent thrombosis was considerably low (<=1.0%) for all types of DES, between-group differences were observed, generally favoring the EES platforms.

CONCLUSIONS In this pooled analysis of 3 prospective registries involving unrestricted use of various second-generation DES for LMCAD, we found no significant between-group differences in 3-year risk of target-vessel failure, except for a higher risk of primary outcome with PtCr-EES compared to BP-BES. (Evaluation of the First, Second, and New Drug-Eluting Stents in Routine Clinical Practice [IRIS-DES]; NCT01186133) (J Am Coll Cardiol 2018;71:832-41) © 2018 by the American College of Cardiology Foundation.
Population and Inclusion Criteria

- The study population were pooled from two large-scaled, independent, multicenter, observational studies of the IRIS-MAIN and IRIS-DES registry.

1. Distal LM bifurcation stenosis >50% with ischemic symptom or positive stress test
2. Medina type 1,1,1 or 0,1,1
3. LAD and LCX diameter both > 2.5mm
Study Population

17,196 patients from IRIS-DES and 5,833 patients from IRIS-MAIN (n=23,129)

Exclusion
- Non-bifurcation lesion (n=15,747)
- Non-LM lesion (n=5,050)
- Non-“true” LM bifurcation lesion (n=1,230)

A total of 1,002 patients who underwent PCI with “true” LM bifurcation lesion

440 patients who underwent PCI with simple strategy (single stent technique)

562 patients who underwent PCI with complex strategy (two stent technique)
Primary Endpoint

- Target-vessel failure: a composite of cardiac death, target-vessel MI, or clinically-indicated target-vessel revascularization [TVR]

Secondary Endpoints

- death (cardiac or non-cardiac), MI (Q-wave or Non-Q-wave), repeat revascularization (TVR or non-TVH), and stent thrombosis.
## Baseline Clinical Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Unadjusted Data</th>
<th>IPTW-Adjusted</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1-stent (n = 440)</td>
<td>2-stent (n = 562)</td>
</tr>
<tr>
<td>Age, year</td>
<td>64.4 ± 10.5</td>
<td>64.4 ± 9.8</td>
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<tr>
<td>Male sex, n (%)</td>
<td>340 (77.3)</td>
<td>438 (77.9)</td>
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<tr>
<td>Body mass index, kg/m²</td>
<td>24.2 ± 3.0</td>
<td>24.7 ± 2.9</td>
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<tr>
<td>Hypertension</td>
<td>280 (63.6)</td>
<td>361 (64.2)</td>
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<tr>
<td>Diabetes mellitus</td>
<td>172 (39.1)</td>
<td>198 (35.2)</td>
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<tr>
<td>Current smoking</td>
<td>123 (28.0)</td>
<td>135 (24.0)</td>
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<tr>
<td>Hyperlipidemia</td>
<td>64 (14.5)</td>
<td>53 (9.4)</td>
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<tr>
<td>Previous MI</td>
<td>29 (6.6)</td>
<td>50 (8.9)</td>
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<tr>
<td>Previous PCI</td>
<td>77 (17.5)</td>
<td>121 (21.5)</td>
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<tr>
<td>Previous stroke</td>
<td>35 (8.0)</td>
<td>42 (7.5)</td>
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<tr>
<td>Previous heart failure</td>
<td>17 (3.9)</td>
<td>10 (1.8)</td>
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</table>
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<tr>
<td></td>
<td>1-stent ((n = 440))</td>
<td>2-stent ((n = 562))</td>
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<tr>
<td>Chronic renal failure</td>
<td>11 (2.5)</td>
<td>20 (3.6)</td>
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<td>Clinical presentation</td>
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<tr>
<td>Stable angina</td>
<td>206 (46.8)</td>
<td>274 (48.8)</td>
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<tr>
<td>Unstable angina</td>
<td>145 (33.0)</td>
<td>206 (36.7)</td>
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<tr>
<td>MI</td>
<td>89 (20.2)</td>
<td>82 (14.6)</td>
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<tr>
<td>EF Mean, %</td>
<td>58.8 ± 10.5</td>
<td>59.6 ± 9.8</td>
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<td>Discharge medications</td>
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<tr>
<td>Aspirin</td>
<td>427 (97.0)</td>
<td>557 (99.1)</td>
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<tr>
<td>ADP receptor antagonist</td>
<td>420 (95.5)</td>
<td>542 (96.4)</td>
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<tr>
<td>β-blocker</td>
<td>248 (56.4)</td>
<td>312 (55.5)</td>
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<td>Calcium channel blocker</td>
<td>212 (48.2)</td>
<td>268 (47.7)</td>
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<td>ACE inhibitor or ARB</td>
<td>204 (46.4)</td>
<td>254 (45.2)</td>
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<tr>
<td>Statin</td>
<td>167 (38.0)</td>
<td>221 (39.3)</td>
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### Angiographic and Procedural Characteristics

<table>
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<tr>
<th>Characteristic</th>
<th>Unadjusted Data</th>
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<tbody>
<tr>
<td></td>
<td>1-stent (n = 440)</td>
<td>2-stent (n = 562)</td>
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<tr>
<td>Disease extent</td>
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<tr>
<td>2-vessel disease</td>
<td>327 (74.3)</td>
<td>430 (76.5)</td>
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<tr>
<td>3-vessel disease</td>
<td>113 (25.7)</td>
<td>132 (23.5)</td>
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<tr>
<td>Medina</td>
<td></td>
<td></td>
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<tr>
<td>1.1.1</td>
<td>412 (93.6)</td>
<td>525 (93.4)</td>
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<tr>
<td>0.1.1</td>
<td>28 (6.4)</td>
<td>37 (6.6)</td>
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<tr>
<td>Use of IVUS</td>
<td>323 (73.4)</td>
<td>432 (76.9)</td>
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## Angiographic and Procedural Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>1-stent ((n = 440))</th>
<th>2-stent ((n = 562))</th>
<th>(P)</th>
<th>1-stent ((n = 440))</th>
<th>2-stent ((n = 562))</th>
<th>(P)</th>
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<tr>
<td>DES type</td>
<td>0.47</td>
<td>0.93</td>
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<td>1\textsuperscript{st}-generation</td>
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<tr>
<td>SES</td>
<td>94 (21.4)</td>
<td>151 (26.9)</td>
<td></td>
<td>107 (24.4)</td>
<td>139 (24.7)</td>
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<tr>
<td>PES</td>
<td>5 (1.1)</td>
<td>5 (0.9)</td>
<td></td>
<td>5 (1.2)</td>
<td>4 (0.8)</td>
<td></td>
</tr>
<tr>
<td>2\textsuperscript{nd}-generation</td>
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<td></td>
<td></td>
<td></td>
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<tr>
<td>CoCr-EES</td>
<td>118 (26.8)</td>
<td>147 (26.2)</td>
<td></td>
<td>112 (25.4)</td>
<td>151 (26.9)</td>
<td></td>
</tr>
<tr>
<td>PtCr-EES</td>
<td>82 (18.6)</td>
<td>105 (18.7)</td>
<td></td>
<td>80 (18.1)</td>
<td>107 (19.0)</td>
<td></td>
</tr>
<tr>
<td>PC-ZES</td>
<td>73 (16.6)</td>
<td>81 (14.4)</td>
<td></td>
<td>70 (15.8)</td>
<td>83 (14.8)</td>
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<tr>
<td>Re-ZES</td>
<td>28 (6.4)</td>
<td>21 (3.7)</td>
<td></td>
<td>27 (6.0)</td>
<td>25 (4.4)</td>
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<tr>
<td>BES</td>
<td>32 (7.3)</td>
<td>36 (6.4)</td>
<td></td>
<td>30 (6.9)</td>
<td>37 (6.7)</td>
<td></td>
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<tr>
<td>Others</td>
<td>8 (1.8)</td>
<td>16 (2.8)</td>
<td></td>
<td>10 (2.1)</td>
<td>15 (2.7)</td>
<td></td>
</tr>
</tbody>
</table>
Unadjusted 3-Year Event Rate of Clinical Outcome

TVF

**P=0.96**

Death

**P=0.12**

MI

**P=0.65**

Revascularization

**P=0.47**
IPTW-Adjusted Outcomes

**TVF**
- Cumulative incidence over months.
- **P=0.63**

**Death**
- Cumulative incidence over months.
- **P=0.76**

**MI**
- Cumulative incidence over months.
- **P=0.91**

**Revascularization**
- Cumulative incidence over months.
- **P=0.40**
PS Matching-Adjusted Outcome

**TVF**

- P = 0.81

**Death**

- P = 0.46

**MI**

- P = 0.65

**Revascularization**

- P = 0.44
Better Strategy for Distal LM bifurcation?

EBC-MAIN Trial

The European Bifurcation Club Left Main Stenosis Trial: rationale and design of an international, multicenter, randomised comparison of two stent strategies for treatment of left main coronary bifurcation.
2-Stent Bifurcation Techniques for Distal Left Main Disease

- DKCRUSH, Mini-crush (or step crush)
- T-stent, modified T-stent or TAP
- Culotte, Szabo Culotte
- V-stent
- Y-stent (SKS-simultaneous kissing stents)
- Etc…
Any Different Outcomes? with Different 2 Stent Techniques

- Different Indications,
- Very Limited Data,
- Small Difference in Soft End Point (Late Loss, TLR, Branch Restenosis) without Any Hard Endpoint Difference (Death or MI).
IVUS Impact in LM Bifurcation PCI: Effective Stent Area – 2 Stent PCI (Rule of 5,6,7,8 mm²)

Restenosis Rate < 5% and TLR < 2%

IVUS-guided PCI in EXCEL Trial: 690/935 pts (74%)

Change in LM stenting by IVUS

- Used larger balloon: 30% (107)
- Post-dilated: 29% (102)
- Used higher pressure: 17% (62)
- Treated stent under-expansion: 16% (57)
- Led to provisional 1 stent strategy rather than planned 2 stents: 11% (41)
- Led to planned 2 stent strategy rather than provisional 1 stent: 9% (33)

Maehara A. TCT 2016
IVUS Guidance Saves Lives in Left Main PCI

Safety and Effectiveness of Second-Generation Drug-Eluting Stents in Patients With Left Main Coronary Artery Disease

CENTRAL ILLUSTRATION Comparison Between Outcomes of Different Types of Drug-Eluting Stents in the Propensity-Score Analyses: Adjusted HR

<table>
<thead>
<tr>
<th>A</th>
<th>Target-Vessel Failure</th>
<th>B</th>
<th>Major Adverse Cardiac Event</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Adjusted HR (95% CI)</td>
<td></td>
<td>Adjusted HR (95% CI)</td>
</tr>
<tr>
<td>BP-BES vs. CoCr-EES</td>
<td>0.72 (0.46-1.12)</td>
<td>BP-BES vs. CoCr-EES</td>
<td>0.85 (0.58-1.23)</td>
</tr>
<tr>
<td>PtCr-EES vs. CoCr-EES</td>
<td>1.15 (0.90-1.47)</td>
<td>PtCr-EES vs. CoCr-EES</td>
<td>1.08 (0.86-1.36)</td>
</tr>
<tr>
<td>Re-ZES vs. CoCr-EES</td>
<td>0.88 (0.67-1.15)</td>
<td>Re-ZES vs. CoCr-EES</td>
<td>0.91 (0.71-1.16)</td>
</tr>
</tbody>
</table>

0.1 1 10
Favor Non-CoCr-EES Favor CoCr-EES

0.1 1 10
Favor Non-CoCr-EES Favor CoCr-EES

Current PCI for Distal LM bifurcation

Algorithm for Left Main Bifurcation Intervention

LM Bifurcation

- **Simple lesion**
  - SB lesion <70% and/or lesion length <10 mm
  - Easy SB access

- **Complex lesion**
  - SB lesion ≥70% and/or lesion length >10 mm

**Provisional or Inverted Provisional (EBC consensus)**

- 2 stents
  - SB stent first Inverted Culotte

- 1 stent
  - SB compromise FFR <0.80 <TIMI 3 flow

**2 stents T/TAP or Culotte**

**2 stents SB stent first DK-Crush (ABC consensus)**

**IVUS/OCT imaging strongly recommended after LM Stenting**

Distal LM Bifurcation PCI
How To Do?

- Provisional approach is recommended in most of distal LM disease.
- According to the status of SB (LCX) disease, either 1- or any 2-stent strategy is selected in the contemporary PCI with second-generation DES.
- Side branch strategy with functional concept (FFR-guided) can make a good clinical outcomes.
- Whatever you used 2-stent technique, imaging concept (IVUS optimization-effective stent area, 5.6.7.8 mm²) can make a good clinical outcomes.