One-Month Dual Antiplatelet Therapy Followed by Clopidogrel Monotherapy versus Standard 12-Month Dual Antiplatelet Therapy with Clopidogrel After Drug-Eluting Stent Implantation:

STOPDAPT-2

Hirotoshi Watanabe
Takenori Domei, Takeshi Morimoto, Hiroki Shiomi, Masahiro Natsuaki, Toshiaki Toyota, Kensuke Takagi, Yoshiki Hata, Satoru Suwa, Mamoru Nanasato, Masanobu Ohya, Masahiro Yagi, Takafumi Yokomatsu, Mitsuru Abe, Kenji Ando, Kazushige Kadota, Ken Kozuma, Yoshihiro Morino, Yuji Ikari, Kengo Tanabe, Koichi Nakao, Kazuya Kawai, Yoshihisa Nakagawa, and Takeshi Kimura, on behalf of STOPDAPT-2 investigators
Background

- Mandatory 1-month DAPT had been the standard care after BMS implantation.
- DAPT duration was prolonged after introduction of DES without firm scientific evidence.
- New generation DES has substantially reduced stent thrombosis.
- Prolonged DAPT is inevitably associated with increase in bleeding.
- Bleeding is associated with subsequent mortality risk at least comparable to that of MI.

Therefore, very short mandatory DAPT duration after DES might be an attractive option, if not associated with increase in ischemic events disproportionate to the reduction in bleeding events.
STOPDAPT

Prospective multicenter open-label single arm trial evaluating 3-month DAPT after CoCr-EES implantation

**Primary Endpoint**
Cardiovascular death, MI, Stroke, Definite ST, and Bleeding

**Adjusted HR 0.64 (0.42-0.95)**

P=0.03

Objective

The objective of the STOPDAPT-2 trial is to explore the safety and efficacy of the experimental regimen of 1-month DAPT followed by clopidogrel monotherapy as compared with the standard 12-month DAPT with aspirin and clopidogrel after implantation of cobalt-chromium everolimus-eluting stents (CoCr-EES).
STOPDAPT-2:
Prospective multicenter open-label randomized trial comparing 1-month versus 12-month DAPT after CoCr-EES implantation with limited exclusion criteria.

1-month DAPT group

- PCI
- ASA
- P2Y12i
- Clopidogrel 75mg/day or Prasugrel 3.75 mg/day

1M (30-59d)

- Clopidogrel 75mg/d

1Y (335-394d)

Primary analysis for Non-inferiority

5Y

12-month DAPT group

- ASA
- P2Y12i
- Clopidogrel 75mg/d

ASA
Study Organization

Steering Committee
Takeshi Kimura (PI)
Kazushige Kadota
Ken Kozuma
Yoshihiro Morino
Keiichi Igarashi-Hanaoka
Yuji Ikari
Kengo Tanabe
Kenji Ando
Koichi Nakao
Kazuya Kawai
Mitsuru Abe

Clinical Event Committee
Yoshihisa Nakagawa
Yutaka Furukawa
Masahiro Natsuaki
Hiroki Shiomi
Toshiaki Toyota

Safety Evaluation Committee
Shunichi Miyazaki
Ryuji Nohara

Angiography Core Laboratory
Cardio Core Japan, Tokyo, Japan

Study administrative staff
Masahiro Natsuaki
Hirotoshi Watanabe
Toshiaki Toyota
Toshikazu Jinnai

Funded by
Abbott Vascular Japan, Co., Ltd.

Trial Statistician
Takeshi Morimoto

Coordinating Center
Research Institute for Production Development, Kyoto, Japan
Saori Tezuka
Yumika Fujino
90 Participating Centers

Teine Keijinkai Hospital
Hokko Memorial Hospital
Hirosaki University Hospital
Iwate Medical University Hospital
Sendai Kousei Hospital
Sendai Cardiovascular Center
Tohoku Medical and Pharmaceutical University Hospital
Nakadori General Hospital
Nihonkai General Hospital
Hoshi General Hospital
Jichi Medical University Hospital
Mashiko Hospital
Mitsui Memorial Hospital
Juntendo University Hospital
The Fraternity Memorial Hospital
Edogawa Hospital
Showa University Koto Toyosu Hospital
Tokyo Women's Medical University Hospital
Tokyo General Hospital
Juntendo University Nerima Hospital
Kawakita General Hospital
Sakakibara Heart Institute
Tokyo Metropolitan Tama Medical Center
Minamino Cardiovascular Hospital
Higashiyamato Hospital
St.Marianna University School of Medicine Hospital
Yokohama Rosai Hospital
Showa University Fujigaoka Hospital
Saiseikai Yokohamashi Tobu Hospital
Yokohama City University Medical Center

Kitasato University Hospital
Hiratsuka Kyouai Hospital
Tokai University Hospital
Kimitsu Chuou Hospital
Kanazawa Cardiovascular Hospital
University of Fukui Hospital
Municipal Tsuruga Hospital
University of Yamanashi Hospital
Gifu Prefectural General Medical Center
Ogaki Municipal Hospital
Juntendo University Shizuoka Hospital
Shizuoka General Hospital
Japanese Red Cross Nagoya Daini Hospital
Handa City Hospital
Tosei General Hospital
Ichinomiyanishi Hospital
Yokkaichi Hazu Medical Center
Matsusaka Central General Hospital
Nabari City Hospital
Otsu Red Cross Hospital
Hikone Municipal Hospital
Kyoto University Hospital
Kyoto Medical Center
Mitsubishi Kyoto Hospital
Kitano Hospital
Osaka Red Cross Hospital
National Cerebral and Cardiovascular Center
Kindai University Hospital
Mimihara General Hospital
Bell Land General Hospital

Kobe City Medical Center General Hospital
Kindai University Nara Hospital
Tenri Hospital
Japanese Red Cross Wakayama Medical Center
Wakayama Medical University Hospital
Shimane University Hospital
Japanese Red Cross Okayama Hospital
Kurashiki Central Hospital
Hirosima University Hospital
Iwakuni Medical Center
Tokuyama Central Hospital
Shimonoseki City Hospital
Tokushima University Hospital
Tokushima Red Cross Hospital
Kagawa Prefectural Central Hospital
Ehime Prefectural Central Hospital
Matsuyama Red Cross Hospital
Chikamori Hospital
Kokura Memorial Hospital
Hospital of University of Occupational and Environmental Health Japan
Saiseikai Fukuoka General Hospital
Fukuoka Tokushukai Hospital
Kumamoto University Hospital
Saiseikai Kumamoto Hospital
Japanese Red Cross Kumamoto Hospital
Miyazaki Prefectural Noeoka Hospital
Ibusuki Medical Center
Izumi Regional Medical Center
Urasoe General Hospital
Nakagami Hospital
Inclusion Criteria

• PCI with exclusive use of CoCr-EES (Xience™ series)
• No major complications during hospitalization for index PCI
• No plan for staged PCI
• Patients who could take DAPT with aspirin and P2Y₁₂ inhibitors

Key Exclusion Criteria

• Needs for oral anticoagulants
• History of intracranial hemorrhage
Endpoints

- **Primary endpoint:**
  
  Net adverse cardiovascular events (NACE: Ischemia and Bleeding)
  
  - A composite of cardiovascular death, MI, Definite ST, Stroke,
    or TIMI major/minor bleeding

- **Major secondary endpoints:**

  Ischemic composite endpoint
  
  - A composite of cardiovascular death, MI, Definite ST, or Stroke

  Bleeding endpoint
  
  - TIMI major/minor bleeding
Sample Size Calculation

• Hypothesis: Non-inferiority of 1-month DAPT to 12-month DAPT for the primary endpoint at 1-year

• Assumption: Event rate at 1-year: 4.6% (Based on RESET study).

• Non-inferiority margin; 50% on the hazard ratio scale

• Randomization ratio: 1:1

• One-sided alpha: 0.025

• Power: 85%

• Sample size: 3000 patients (1500 in each arm)
Study Flow

**Eligible patients**
PCI exclusively with CoCr-EES/No scheduled staged PCI
Dec. 2015-Dec. 2017
N=6504

**Enrolled and randomized**
N=3045

- 36 withdrawal

**Participants**
N=3009

**Non-Participants**
with demographic data
N=3287

3459 did not participate
- 1731 Physicians’ judgement
- 1280 Patients’ refusal
- 362 Logistic reasons
- 47 Ethical reasons
- 39 Unknown

172 Data missing
### Participants vs Non-participants

<table>
<thead>
<tr>
<th></th>
<th>Participants N=3009</th>
<th>Non-participants N=3287</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>68.6±10.7</td>
<td>70.0±11.7</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>ACS</td>
<td>38%</td>
<td>39%</td>
<td>0.61</td>
</tr>
<tr>
<td>STEMI</td>
<td>19%</td>
<td>22%</td>
<td>0.003</td>
</tr>
<tr>
<td>Prior MI</td>
<td>14%</td>
<td>23%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Prior 1st-generation DES implantation</td>
<td>4%</td>
<td>6%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Diabetes</td>
<td>39%</td>
<td>39%</td>
<td>0.47</td>
</tr>
<tr>
<td>Severe CKD</td>
<td>6%</td>
<td>9%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Dialysis</td>
<td>3%</td>
<td>5%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Target of LMCA</td>
<td>3%</td>
<td>5%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Two or more target vessels</td>
<td>7%</td>
<td>9%</td>
<td>0.003</td>
</tr>
</tbody>
</table>
Study Flow

Eligible patients
Dec. 2015-Dec. 2017
N=6504

Enrolled and randomized
N=3045

Stratified by Center

1-month DAPT arm
N=1523

23 withdrew consent

ITT population
N=1500

Complete 1-Year FU
N=1478 (98.5%)

12-month DAPT arm
N=1522

13 withdrew consent

ITT population
N=1509

Complete 1-Year FU
N=1496 (99.1%)

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47 Ethical reasons
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39 Unknown
# Baseline Clinical Characteristics

<table>
<thead>
<tr>
<th></th>
<th>1-month DAPT N=1500</th>
<th>12-month DAPT N=1509</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, years</td>
<td>68.1±10.9</td>
<td>69.1±10.4</td>
</tr>
<tr>
<td>Men</td>
<td>79%</td>
<td>77%</td>
</tr>
<tr>
<td>ACS</td>
<td>38%</td>
<td>39%</td>
</tr>
<tr>
<td>STEMI</td>
<td>19%</td>
<td>18%</td>
</tr>
<tr>
<td>Stable CAD</td>
<td>62%</td>
<td>61%</td>
</tr>
<tr>
<td>Diabetes</td>
<td>39%</td>
<td>38%</td>
</tr>
<tr>
<td>Severe CKD (eGFR&lt;30ml/min/m²)</td>
<td>6%</td>
<td>6%</td>
</tr>
<tr>
<td>Prior MI</td>
<td>14%</td>
<td>13%</td>
</tr>
<tr>
<td>Prior PCI</td>
<td>34%</td>
<td>35%</td>
</tr>
<tr>
<td>CREDO-Kyoto thrombotic risk score</td>
<td></td>
<td></td>
</tr>
<tr>
<td>High; Intermediate; Low</td>
<td>8%; 21%; 71%</td>
<td>8%; 24%; 68%</td>
</tr>
<tr>
<td>CREDO-Kyoto bleeding risk score</td>
<td></td>
<td></td>
</tr>
<tr>
<td>High; Intermediate; Low</td>
<td>7%; 27%; 66%</td>
<td>7%; 27%; 66%</td>
</tr>
</tbody>
</table>
## Procedural Characteristics and Medications

<table>
<thead>
<tr>
<th></th>
<th>1-month DAPT N=1500</th>
<th>12-month DAPT N=1509</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transradial approach</td>
<td>82%</td>
<td>84%</td>
</tr>
<tr>
<td>N of target lesions</td>
<td>1.12 ± 0.35</td>
<td>1.14 ± 0.39</td>
</tr>
<tr>
<td>Minimal stent diameter, mm</td>
<td>2.98 ± 0.49</td>
<td>2.96 ± 0.48</td>
</tr>
<tr>
<td>Total stent length, mm</td>
<td>30.3 ± 16.7</td>
<td>30.5 ± 16.8</td>
</tr>
<tr>
<td>SYNTAX Score</td>
<td>8 (5-14)</td>
<td>9 (6-15)</td>
</tr>
<tr>
<td>Target of LMCA</td>
<td>3%</td>
<td>3%</td>
</tr>
<tr>
<td>CTO</td>
<td>4%</td>
<td>4%</td>
</tr>
<tr>
<td>IVUS or OCT</td>
<td>97%</td>
<td>98%</td>
</tr>
<tr>
<td>ASA</td>
<td>99.8%</td>
<td>100%</td>
</tr>
<tr>
<td>Clopidogrel</td>
<td>60%</td>
<td>63%</td>
</tr>
<tr>
<td>Prasugrel (3.75mg/day)</td>
<td>40%</td>
<td>37%</td>
</tr>
<tr>
<td>Statin</td>
<td>88%</td>
<td>87%</td>
</tr>
<tr>
<td>PPI</td>
<td>79%</td>
<td>79%</td>
</tr>
</tbody>
</table>
Persistent DAPT discontinuation rate

Cumulative incidence

Number of patients on DAPT

<table>
<thead>
<tr>
<th></th>
<th>1-month DAPT</th>
<th>12-month DAPT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Days after index PCI</td>
<td>1-month DAPT</td>
<td>12-month DAPT</td>
</tr>
<tr>
<td>0-30 days</td>
<td>1500 1346 67</td>
<td>1509 1499 1467</td>
</tr>
<tr>
<td>30-60 days</td>
<td>38 32 28 25 23 9</td>
<td>1442 1412 1387 1352 1314 178</td>
</tr>
<tr>
<td>60-90 days</td>
<td>95.5%</td>
<td>85.9%</td>
</tr>
<tr>
<td>90-180 days</td>
<td>2.1%</td>
<td>11.9%</td>
</tr>
<tr>
<td>180-365 days</td>
<td>98.8%</td>
<td>85.9%</td>
</tr>
</tbody>
</table>
Primary Endpoint: Net clinical benefit
CV death/MI/ST/Stroke/TIMI major/minor bleeding

HR 0.64, 95%CI (0.42-0.98)
P non-inferiority <0.001
P superiority =0.04

Log rank P=0.037

No. at risk
12-month DAPT 1509 1501 1486 1481 1469 1458 1442 1458 1159
1-month DAPT 1500 1494 1479 1475 1468 1453 1441 1151
Major secondary ischemic endpoint
CV death/MI/ST/Stroke

HR 0.79, 95%CI (0.49-1.29)
P non-inferiority = 0.005
P superiority = 0.34

Log rank P = 0.34
Major secondary bleeding endpoint
TIMI major/minor bleeding

HR 0.26, 95%CI (0.11-0.64)
P superiority =0.004

Log rank P=0.002
Clinical Outcomes at 1 year

P values for superiority

- Death: P=0.61
- MI: P=0.66
- Definite ST: P=0.57
- Probable ST: P=0.11
- Stroke: P=0.004
- TIMI major/minor Bleeding: P=0.003
- BARC 3 or 5 Bleeding: P=0.11

* 2 cases of probable ST (undefined death) in the 1-month DAPT group occurred before discontinuing DAPT at 1-month
### Subgroup Analysis for the Primary Endpoint (1)

**1-month DAPT (N=1500) vs. 12-month DAPT (N=1509)**

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>1-month DAPT</th>
<th>12-month DAPT</th>
<th>HR (95%CI)</th>
<th>P superiority</th>
<th>P interaction</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt;=75 years</td>
<td>10/448 (2.26%)</td>
<td>25/499 (5.08%)</td>
<td>0.44 (0.21-0.92)</td>
<td>0.03</td>
<td>0.20</td>
</tr>
<tr>
<td>&lt;75 years</td>
<td>25/1052 (2.41%)</td>
<td>30/1010 (3.02%)</td>
<td>0.80 (0.47-1.36)</td>
<td>0.41</td>
<td></td>
</tr>
<tr>
<td><strong>ACS</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>16/565 (2.88%)</td>
<td>23/583 (4.02%)</td>
<td>0.72 (0.38-1.36)</td>
<td>0.44</td>
<td>0.64</td>
</tr>
<tr>
<td>No</td>
<td>19/935 (2.05%)</td>
<td>32/926 (3.49%)</td>
<td>0.59 (0.33-1.03)</td>
<td>0.06</td>
<td></td>
</tr>
<tr>
<td><strong>STEMI</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>9/291 (3.15%)</td>
<td>14/270 (5.26%)</td>
<td>0.60 (0.26-1.38)</td>
<td>0.23</td>
<td>0.87</td>
</tr>
<tr>
<td>No</td>
<td>26/1209 (2.18%)</td>
<td>41/1239 (3.36%)</td>
<td>0.65 (0.40-1.06)</td>
<td>0.08</td>
<td></td>
</tr>
<tr>
<td><strong>Severe CKD</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>9/82 (11.22%)</td>
<td>5/84 (5.97%)</td>
<td>1.93 (0.65-5.75)</td>
<td>0.24</td>
<td>0.03</td>
</tr>
<tr>
<td>No</td>
<td>26/1418 (1.86%)</td>
<td>50/1425 (3.56%)</td>
<td>0.52 (0.32-0.84)</td>
<td>0.007</td>
<td></td>
</tr>
<tr>
<td><strong>Diabetes</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>18/585 (3.12%)</td>
<td>25/574 (4.45%)</td>
<td>0.70 (0.38-1.29)</td>
<td>0.26</td>
<td>0.65</td>
</tr>
<tr>
<td>No</td>
<td>17/915 (1.88%)</td>
<td>30/935 (3.24%)</td>
<td>0.58 (0.32-1.05)</td>
<td>0.07</td>
<td></td>
</tr>
<tr>
<td><strong>Total stent length &gt;=28mm</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>19/742 (2.60%)</td>
<td>33/787 (4.23%)</td>
<td>0.61 (0.35-1.07)</td>
<td>0.08</td>
<td>0.76</td>
</tr>
<tr>
<td>No</td>
<td>16/758 (2.14%)</td>
<td>22/722 (3.12%)</td>
<td>0.69 (0.36-1.32)</td>
<td>0.26</td>
<td></td>
</tr>
<tr>
<td><strong>Two or more target vessels</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>4/100 (4.14%)</td>
<td>8/116 (6.94%)</td>
<td>0.58 (0.17-1.92)</td>
<td>0.37</td>
<td>0.85</td>
</tr>
<tr>
<td>No</td>
<td>31/1400 (2.24%)</td>
<td>47/1393 (3.43%)</td>
<td>0.66 (0.42-1.03)</td>
<td>0.07</td>
<td></td>
</tr>
<tr>
<td><strong>Overall</strong></td>
<td>35/1500 (2.36%)</td>
<td>55/1509 (3.70%)</td>
<td>0.64 (0.42-0.98)</td>
<td>0.038</td>
<td></td>
</tr>
</tbody>
</table>

**Graphical Representation:**

- **1-month DAPT better** vs. **12-month DAPT better**
  - **HR (95%CI)**: Comparing the Hazard Ratio between 1-month and 12-month DAPT for each subgroup.
  - **P superiority** and **P interaction** indicate statistical significance and interaction between subgroups.
## Subgroup analysis for the primary endpoint (2)

### PARIS thrombotic risk score

<table>
<thead>
<tr>
<th></th>
<th>1-month DAPT (N=1500)</th>
<th>12-month DAPT (N=1509)</th>
<th>HR (95%CI)</th>
<th>P superiority</th>
<th>P interaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intermediate/High</td>
<td>26/771 (3.43%)</td>
<td>37/751 (5.00%)</td>
<td>0.68 (0.41-1.13)</td>
<td>0.14</td>
<td>0.56</td>
</tr>
<tr>
<td>Low</td>
<td>9/729 (1.24%)</td>
<td>18/758 (2.40%)</td>
<td>0.52 (0.23-1.15)</td>
<td>0.11</td>
<td>0.56</td>
</tr>
</tbody>
</table>

### CREDO-Kyoto thrombotic risk score

<table>
<thead>
<tr>
<th></th>
<th>1-month DAPT (N=1500)</th>
<th>12-month DAPT (N=1509)</th>
<th>HR (95%CI)</th>
<th>P superiority</th>
<th>P interaction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intermediate/High</td>
<td>15/431 (3.55%)</td>
<td>30/480 (6.31%)</td>
<td>0.55 (0.30-1.03)</td>
<td>0.06</td>
<td>0.45</td>
</tr>
<tr>
<td>Low</td>
<td>20/1069 (1.89%)</td>
<td>25/1029 (2.47%)</td>
<td>0.77 (0.43-1.39)</td>
<td>0.38</td>
<td>0.45</td>
</tr>
</tbody>
</table>

### Overall

<table>
<thead>
<tr>
<th></th>
<th>1-month DAPT (N=1500)</th>
<th>12-month DAPT (N=1509)</th>
<th>HR (95%CI)</th>
<th>P superiority</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>35/1500 (2.36%)</td>
<td>55/1509 (3.70%)</td>
<td>0.64 (0.42-0.98)</td>
<td>0.038</td>
</tr>
</tbody>
</table>
Limitations

- Lack of consensus on the use of the NACE as primary endpoint
- Open label design with its inherent limitations
- Limited enrollment of high ischemic risk patients
- Lower ischemic risk of Japanese versus US/European CAD patients
- Ticagrelor / Prasugrel (standard dose) not available in Japan
- No assessment of aspirin monotherapy after 1-month DAPT
Conclusions

One-month DAPT followed by clopidogrel monotherapy provided a net clinical benefit for ischemic and bleeding events over 12-month DAPT with aspirin and clopidogrel after CoCr-EES implantation.

The benefit was driven by significant reduction in bleeding events without increase in ischemic events.