Recent Progress of CTO Intervention and Long-term Outcome After DES Implantation in CTO

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Disclosure of Conflicts

Nothing to disclose regarding in this presentation.
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CTO: Top of the Mountain

Complex Subsets

Small vessel

Long lesion

Ostial lesion

ISR

Bifurcation

LMT

CTO
Changes of CTO Techniques and Success Rate

Cases

Success rate


Conquest wire

Parallel wire method

TORNUS system

Retro A

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Technical Aspect of CTO Intervention
Recent Progress of PCI for CTO

(1) Technique
1. Parallel wire technique
2. Anchor balloon technique
3. Retrograde approach
4. IVUS guide approach

- Well Understanding of CTO from Pathological and Physiological findings by CTA etc.
- Findings from a lot of experience based evidence of Retrograde Approach.
Recent Progress of PCI for CTO

- Big shift in Japan “Antegrade→Retrograde” approach” in CTO strategy (~40%)
- Big shift in Japan “Usage of Hydrophilic Wire More and More” in case of Antegrade approach
- CART technique, Reverse CART technique
  ……And so many technique relating
  Retrograde approach was introduced
Recent Progress of PCI for CTO

(2) Device

1. Development of Guidewire
   - **Hard type:** Miracle Guidewire (3, 6, 12g): Asahi Intec Co
   - Conquest Guidewire (9, 12, 8-20): Asahi Intec Co
   - Athlete Magic Guidewire: JapanLifeLine
   - **Soft type:** Fielder FC, XT Guidewire
   - Other Company 10 system (Thin-GW)

2. Tornus catheter system
   - Tornus (regular, 88system), Channel Dilator (Crossair)

3. Balloon and Microtube-cath ……Many !!!!!

4. DES …….Many
From technical point of view, most important point of PCI of CTO is to Open the CTO with high success rate and without any complication.

You should select the appropriate technique which you are familiar with and is highly probable way to success. Even Retro or Antegrade ??
We already confirmed the short-term efficacy of DES regarding reducing the restenosis.

Remaining Subjects

1. Long-term durability
2. Other DES also effective?
3. Stent Thrombosis
Four-Year Durability of Sirolimus-Eluting Stent in Patients with Chronic Total Occlusions Compared with Bare Metal Stent: Multicenter Registry in Asia
Patient cohort includes 226 patients with CTOs in our data-base, treated with Sirolimus-eluting stent (SES), Bare Metal Stent (BMS) with 4 years follow up.

Asian Multicenter DES-CTO Registry
Total 796 patients

- SES n=106
  - 2002 March
  - implanted
  - Fin.48 MO. F/U Clinical / Angio.

- BMS n=120
  - 2002 Dec.
4 Years Event Free Survival

All Cause of Death

Death, MI, TVR, TLR

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Comparison of 3 Years Efficacy and Durability of Sirolimus-Eluting Stent and Paclitaxel-Eluting Stent in Patients with Chronic Total Occlusions: Multicenter Registry in Asia

ESC 2008
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2002  2003  2004  2005  2006  2007  2008

Mar  Apr  Jun  Jun  Jun  Jun  Jun  Jun

SESSES
: Asian Multicenter Registry n=838

Patients
221
attempt 420, success 221 (94.2%)

PESPES
: Asian Multicenter Registry n=788

Patients
196
attempt 560, success 196 (93.9%)

Study Patients

3years
3 Years Event Free Survival

All Cause of Death

P = 0.8889

MACE

P = 0.2102

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Case 1: RCA CTO

Pre RCA-CTO

6 mo later
Totally occluded

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Remaining Subjects

1. Long-term durability
2. Other DES also effective?
3. Stent Thrombosis
Drug-Eluting Stents for the Treatment of Chronic Total Occlusion: A comparison with Sirolimus, Paclitaxel, Zotarolimus, EPC Capture and Everolimus-Eluting Stent-Multicenter Registry in Asia-

AHA 2008
Patient cohort includes 1,082 patients with CTOs in our data-base, treated with Sirolimus-eluting stent (SES), Paclitaxel-eluting stent (PES), Zotarolimus-eluting stent (ZES), EPC capture stent (ECS) and Everolimus-eluting stent (EES).
Antiplatelet Therapy

1. Aspirin  100 mg / day

2. Clopidogrel  75 mg / day

12 months long
(with loading dose 300 mg: 1 day)

*EPC Capture stent  1 month long
Study Endpoints

Primary End Point

- 30 days MACE
- 12 months MACE

Secondary End Points

- 12 months angiographic restenosis rate
## Baseline Characteristics

<table>
<thead>
<tr>
<th></th>
<th>SES (n=365)</th>
<th>PES (n=482)</th>
<th>ZES (n=154)</th>
<th>ECS (n=39)</th>
<th>EES (n=42)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (yrs:mean)</strong></td>
<td>68.8</td>
<td>67.9</td>
<td>68.9</td>
<td>69.7</td>
<td>69.1</td>
</tr>
<tr>
<td><strong>Male (%)</strong></td>
<td>73.9</td>
<td>70.1</td>
<td>64.9</td>
<td>78.9</td>
<td>71.4</td>
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<tr>
<td><strong>Coronary risk factor (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Hypertension</td>
<td>52.1</td>
<td>51.9</td>
<td>57.8</td>
<td>51.3</td>
<td>50.0</td>
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<tr>
<td>Hyperlipidemia</td>
<td>30.1</td>
<td>27.0</td>
<td>32.4</td>
<td>39.5</td>
<td>38.0</td>
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<tr>
<td>Diabetes mellitus</td>
<td>30.7</td>
<td>28.8</td>
<td>26.0</td>
<td>33.3</td>
<td>33.0</td>
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<tr>
<td>Current smoker</td>
<td>52.1</td>
<td>47.7</td>
<td>64.9</td>
<td>54.5</td>
<td>52.4</td>
</tr>
<tr>
<td><strong>Prior MI (%)</strong></td>
<td>27.4</td>
<td>27.4</td>
<td>24.7</td>
<td>38.5</td>
<td>33.3</td>
</tr>
<tr>
<td><strong>LVEF (%:mean)</strong></td>
<td>47.8</td>
<td>48.3</td>
<td>49.5</td>
<td>47.8</td>
<td>48.8</td>
</tr>
</tbody>
</table>
Angiographic Lesion Characteristics

Numbers of Diseased Vessels

**SES**
- One: 20.3%
- Two: 35.1%
- Three: 44.6%

**PES**
- One: 20.1%
- Two: 40.0%
- Three: 39.9%

**ZES**
- One: 18.8%
- Two: 40.3%
- Three: 40.9%

**ECS**
- One: 15.4%
- Two: 33.3%
- Three: 51.3%

**EES**
- One: 11.9%
- Two: 31.0%
- Three: 57.1%

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Angiographic Lesion Characteristics

Location of CTO

<table>
<thead>
<tr>
<th></th>
<th>SES</th>
<th>PES</th>
<th>ZES</th>
</tr>
</thead>
<tbody>
<tr>
<td>RCA</td>
<td>24.7%</td>
<td>23.7%</td>
<td>27.3%</td>
</tr>
<tr>
<td>LCX</td>
<td>20.2%</td>
<td>18.9%</td>
<td>25.9%</td>
</tr>
<tr>
<td>LAD</td>
<td>50.4%</td>
<td>53.9%</td>
<td>42.9%</td>
</tr>
<tr>
<td>LMT</td>
<td>1.1%</td>
<td>0.8%</td>
<td>0.6%</td>
</tr>
<tr>
<td>Others</td>
<td>3.6%</td>
<td>2.7%</td>
<td>3.3%</td>
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</table>

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## Angiographic and Procedure Characteristics

<table>
<thead>
<tr>
<th></th>
<th>SES (n=365)</th>
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<th>EES (n=42)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reference diameter</td>
<td>2.85</td>
<td>2.81</td>
<td>2.79</td>
<td>2.92</td>
<td>2.92</td>
</tr>
<tr>
<td>(proximal) (mm:mean)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MLD post stenting</td>
<td>2.64</td>
<td>2.57</td>
<td>2.56</td>
<td>2.67</td>
<td>2.70</td>
</tr>
<tr>
<td>(mm:mean)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Angiographic calcification (%)</td>
<td>68.5</td>
<td>58.1</td>
<td>66.2</td>
<td>76.9</td>
<td>71.4</td>
</tr>
<tr>
<td>Side branch: present</td>
<td>27.4</td>
<td>30.1</td>
<td>50.0*</td>
<td>25.6</td>
<td>47.6*</td>
</tr>
<tr>
<td>(%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lesion length</td>
<td>37.5</td>
<td>39.8</td>
<td>35.2</td>
<td>28.9†</td>
<td>27.8†</td>
</tr>
<tr>
<td>(mm:mean)</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Stent length</td>
<td>44.8</td>
<td>47.1</td>
<td>43.8</td>
<td>37.9†</td>
<td>35.5†</td>
</tr>
<tr>
<td>(mm:mean)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Maximal inflation</td>
<td>19.9</td>
<td>19.5</td>
<td>18.9</td>
<td>19.0</td>
<td>19.2</td>
</tr>
<tr>
<td>pressure (atm:mean)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Stent overlap (%)</td>
<td>90.4</td>
<td>87.1</td>
<td>90.3</td>
<td>88.5</td>
<td>88.0</td>
</tr>
</tbody>
</table>

*p<0.05 vs SES, PES and ECS. †p<0.05 vs SES, PES and ZES.
## Clinical Results:

### 30 Days Clinical Outcome

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td><strong>Clinical success (%)</strong></td>
<td>98.7</td>
<td>98.8</td>
<td>98.7</td>
<td>98.7</td>
<td>100</td>
</tr>
<tr>
<td><strong>MACE (n)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>QMI</td>
<td>2</td>
<td>3</td>
<td>3</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Urgent CABG</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Urgent PCI</td>
<td>2 (SAT)</td>
<td>3 (SAT)</td>
<td>1 (SAT)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>SAT</td>
<td>2</td>
<td>3</td>
<td>1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Cardiac tamponade</td>
<td>2</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

SAT 0.6%  
MI 0.6%
<table>
<thead>
<tr>
<th></th>
<th>SES (n=365)</th>
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<th>EES (n=42)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ref. diameter (mm:mean)</td>
<td>2.85</td>
<td>2.81</td>
<td>2.79</td>
<td>2.92</td>
<td>2.92</td>
</tr>
<tr>
<td>MLD (mm:mean)</td>
<td>2.49</td>
<td>2.33</td>
<td>2.08</td>
<td>2.20</td>
<td>2.50</td>
</tr>
<tr>
<td>Late loss (mm:mean)</td>
<td>0.15</td>
<td>0.24</td>
<td>0.48*</td>
<td>0.47*</td>
<td>0.20</td>
</tr>
<tr>
<td>Loss index (%:mean)</td>
<td>5.7</td>
<td>9.3</td>
<td>18.8*</td>
<td>17.8*</td>
<td>7.4</td>
</tr>
<tr>
<td>Restenosis rate (%)</td>
<td>6.3</td>
<td>9.3</td>
<td>13.0*</td>
<td>15.4*</td>
<td>7.1</td>
</tr>
<tr>
<td>Re-occlusion rate (%)</td>
<td>0</td>
<td>0.8</td>
<td>1.3</td>
<td>2.5</td>
<td>0</td>
</tr>
<tr>
<td>TVR (%)</td>
<td>5.8</td>
<td>9.3</td>
<td>12.3*</td>
<td>12.9*</td>
<td>7.1</td>
</tr>
<tr>
<td>TLR (%)</td>
<td>4.4</td>
<td>8.3</td>
<td>11.0*</td>
<td>10.3*</td>
<td>4.8</td>
</tr>
</tbody>
</table>

*p<0.05 vs SES, EES
Cumulative Distribution Curve of Changing MLD

**SES**
- Binary restenosis rate: 6.9%

**PES**
- Binary restenosis rate: 8.7%

**ECS**
- Binary restenosis rate: 15.4%

**ZES**
- Binary restenosis rate: 13.6%

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## Predictor of Restenosis

<table>
<thead>
<tr>
<th>Predictor of Restenosis</th>
<th>OR</th>
<th>95% CI</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stent length</td>
<td>1.129</td>
<td>1.082 – 1.179</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>EF</td>
<td>0.896</td>
<td>0.868 – 0.925</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Bifurcation</td>
<td>3.669</td>
<td>2.171 – 6.202</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

### Stent (vs PES)

<table>
<thead>
<tr>
<th>Stent</th>
<th>OR</th>
<th>95% CI</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>SES</td>
<td>0.406</td>
<td>0.215 – 0.765</td>
<td>0.0053</td>
</tr>
<tr>
<td>ZES</td>
<td>1.098</td>
<td>0.541 – 2.227</td>
<td>0.7956</td>
</tr>
<tr>
<td>ECS</td>
<td>4.522</td>
<td>1.443 – 14.18</td>
<td>0.0096</td>
</tr>
<tr>
<td>EES</td>
<td>2.214</td>
<td>0.513 – 9.550</td>
<td>0.2865</td>
</tr>
</tbody>
</table>
**Independent Predictor of Thrombosis**

<table>
<thead>
<tr>
<th></th>
<th>OR</th>
<th>95% CI</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesion length</td>
<td>1.072</td>
<td>1.016 – 1.131</td>
<td>0.011</td>
</tr>
<tr>
<td>EF</td>
<td>0.931</td>
<td>0.874 – 0.991</td>
<td>0.026</td>
</tr>
<tr>
<td>Bifurcation</td>
<td>16.30</td>
<td>2.038 – 130.88</td>
<td>0.009</td>
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</table>
### Clinical Results: 12 Mo Clinical Results

<table>
<thead>
<tr>
<th></th>
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<th>EES (n=42)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MACE (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Death</td>
<td>0.3</td>
<td>0.4</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>MI</td>
<td>0.8</td>
<td>0.8</td>
<td>1.3</td>
<td>0.5</td>
<td>0</td>
</tr>
<tr>
<td>LAST</td>
<td><strong>0.5(2)</strong></td>
<td><strong>0.4(2)</strong></td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>CABG</td>
<td>0.5(2)</td>
<td>0.4(2)</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Re-PCI</strong></td>
<td><strong>7.9</strong></td>
<td><strong>9.3</strong></td>
<td><strong>14.3</strong>*</td>
<td><strong>15.4</strong>*</td>
<td><strong>7.1</strong></td>
</tr>
<tr>
<td>Any events (%)</td>
<td><strong>8.7</strong></td>
<td><strong>10.3</strong></td>
<td><strong>15.6</strong>*</td>
<td><strong>16.1</strong>*</td>
<td><strong>7.1</strong></td>
</tr>
</tbody>
</table>

*p<0.05 vs SES, EES
Clinical Results:

12 Mo MACE

- All death
  - SES: 0.3%
  - PES: 0.4%
  - ZES: 0.8%
  - ECS: 0.8%
  - EES: 1.3%

- Cardiac death
  - SES: 0.5%
  - PES: 0.8%
  - ZES: 0.8%
  - ECS: 1.3%
  - EES: 0.5%

- MI
  - SES: 0.3%
  - PES: 0.4%
  - ZES: 0.8%
  - ECS: 0.8%
  - EES: 1.3%
Clinical Results:

12 Mo MACE

* p<0.05 vs SES, EES
Remaining Subjects

1. Long-term durability
2. Other DES also effective?
3. Stent Thrombosis
Clinical Results:

Thrombosis: 12 Mo

SAT 0.6%, LAST 0.4%
Total 1.0 %
Stent Thrombosis in 8809 Pts: Asian races

BMS vs DES

- SAT 0.5%
- LAST 0.2%/year

DES

SAT 0.5%, LAST 0.2%
LAST 0.2%/year
1. Recently we developed the new techniques such as parallel wire technique, sea-saw wiring technique, anchor wire technique, retrograde approach technique and IVUS guide technique to improve the initial clinical success rate of PCI for chronic total occlusions.

2. Treatment of chronic total coronary artery occlusions with the Sirolimus-eluting stent (SES), Paclitaxel-eluting stent (PES), Zotarolimus-eluting stent (ZES), EPC capture stent (ECS) and Everolimus-eluting stent (EES) are safe and feasible.

3. Implantation of the SES, PES, ZES, ECS and EES result in a larger MLD at follow-up and dramatically decrease the restenosis rate and target lesion revascularization.
4. Those clinical benefit in terms of reducing the restenosis due to strongly suppressing neo-intimal hyperplasia are durable at least 4 years (SES).

5. Incidence of Stent thrombosis after implantation of SES, PES, ZES ECS and EES in 1082 CTO cases of Asian population is 0.6% SAT and 0.4% LAST (1 year).

6. Patients treated with SES and EES showed the lesser rate of restenosis rate because of the lesser late loss compared with ZES and ECS.