Clinical outcome 5 years after routine T-Stenting versus provisional T-stenting in the treatment of de novo coronary bifurcation lesions using sirolimus-eluting stents

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Background

Previous studies demonstrated no benefit of systematic double stenting compared with single stenting in de-novo coronary bifurcation lesions (NORDIC; BBK I; BBC;) during short follow-up.

There is a lack of complete long term follow-up comparing single and double stenting.
Objective

We analysed the long term follow-up after percutaneous treatment of coronary bifurcation lesions with sirolimus-eluting stents (CYPHER) routine T-stenting of both main and the side branch reduces the restenosis in the side branch compared with provisional T-stenting.
### Inclusion criteria

- Stable angina pectoris and/or positive stress test
- De novo bifurcated lesion of a native coronary artery
- Reference vessel diameter of 2.5 to 4.0 mm in the main branch and of ≥ 2.25 mm in the side branch
- > 50% diameter stenosis of main branch and/or side branch

### Exclusion criteria

- Acute myocardial infarction within 72 hours
- Contraindication to aspirin, heparin, clopidogrel, stainless steel, sirolimus
- History of bleeding diathesis or coagulopathy
- Intraluminal thrombus, heavy calcification and/or severe tortuosity
Prospective randomized study

April 2005 – August 2006

202 patients with de novo bifurcation lesion

Provisional T-stenting
n = 101

Systematic T-stenting
n = 101

Angiographic follow-up with QCA at 9 months
(“Medis” bifurcation program)

Primary endpoint
In-segment percent diameter stenosis of the side branch at angiographic follow-up

Clinical follow-up at 1, 2 and 5 years
Technical approach

Provisional T-stenting

Routine modified T-stenting

Stent placement in the main branch
Technical approach

Provisional T-stenting

Routine modified T-stenting

Final kissing balloon dilatation
Technical approach

- Provisional T-stenting
- Routine modified T-stenting

Final kissing balloon dilatation
Technical approach

Provisional T-stenting

Routine modified T-stenting
## Baseline demographics

<table>
<thead>
<tr>
<th></th>
<th>Provisional T-Stenting (n = 101)</th>
<th>Routine T-Stenting (n = 101)</th>
<th>( p )-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yrs)</td>
<td>66.7 ± 9.2</td>
<td>66.5 ± 10.5</td>
<td>0.915</td>
</tr>
<tr>
<td>Male sex (%)</td>
<td>79.2</td>
<td>78.2</td>
<td>0.500</td>
</tr>
<tr>
<td>Previous MI (%)</td>
<td>18.8</td>
<td>20.8</td>
<td>0.430</td>
</tr>
<tr>
<td>History of PCI (%)</td>
<td>44.6</td>
<td>51.5</td>
<td>0.199</td>
</tr>
<tr>
<td>2 or 3-vessel disease (%)</td>
<td>65.3</td>
<td>74.2</td>
<td>0.457</td>
</tr>
<tr>
<td>History of CABG (%)</td>
<td>4.0</td>
<td>3.0</td>
<td>0.500</td>
</tr>
<tr>
<td>Ejection fraction (%)</td>
<td>59.1</td>
<td>60.8</td>
<td>0.297</td>
</tr>
<tr>
<td>Diabetes (%)</td>
<td>25.7</td>
<td>18.8</td>
<td>0.155</td>
</tr>
</tbody>
</table>
Distribution of Medina classification

Provisional T-Stenting

True bifurcation = 68%

Systematic T-Stenting

True bifurcation = 68%

p=0.906
## Procedural data

<table>
<thead>
<tr>
<th></th>
<th>Provisional T-Stenting</th>
<th>Systematic T-Stenting</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cross-over (%)</td>
<td>18.8</td>
<td>3.0</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Final kissing balloon (%)</td>
<td>100</td>
<td>100</td>
<td>n.s.</td>
</tr>
</tbody>
</table>
The BBK I - Study: 202 patients - SES - Angiographic Primary Endpoint -

Cumulative distribution (%)

Percent diameter stenosis of the side branch

9.4 %
12.5 %

P = 0.15

Provisional T-Stenting
Routine T-Stenting

Ferenc et al., Eur Heart J 2008
BBK I - TLR 5 years post index-PCI

P = 0.97

Cumulative incidence (%)

0 5 10 15 20

Years after PCI

0 1 2 3 4 5

Provisional T-stenting
Routine T-stenting

16.3 %
16.2 %
BBK I - MACE 5 years post index-PCI

P = 0.91

Cumulative incidence (%) vs Years after PCI

Provisional T-stenting
Routine T-stenting

22.9 %
22.8 %
BBK I - Death / MI 5 years post index-PCI

P = 0.40

Cumulative incidence (%)

Years after PCI

Provisional T-stenting
Routine T-stenting

13.9 %
9.9 %
BBK I - Death 5 years post index-PCI

P = 0.65

Cumulative incidence (%)

Years after PCI

- Provisional T-stenting
- Routine T-stenting

10.0 %
7.9 %
BBK I - probable/definite stent thrombosis
5 years post index-PCI
BBK I - probable/definite stent thrombosis 5 years post index-PCI

Intention-to-treat cohort:
- Routine T-stenting
- Provisional T-stenting

As-treated cohort:
- Double stenting
- Single stenting

Cumulative incidence (\%)

Years after PCI

P=0.25
P=0.02
## BBK I study - Clinical outcome 5 years post PCI - Analysis as treated -

<table>
<thead>
<tr>
<th></th>
<th>Single T-Stenting (n=85)</th>
<th>Double T-Stenting (n=117)</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>TLR (%)</td>
<td>12.0</td>
<td>19.4</td>
<td>0.16</td>
</tr>
<tr>
<td>Any MACE (%)</td>
<td>18.9</td>
<td>25.7</td>
<td>0.26</td>
</tr>
<tr>
<td>Death (%)</td>
<td>7.1</td>
<td>10.3</td>
<td>0.44</td>
</tr>
<tr>
<td>Death and/or MI (%)</td>
<td>9.4</td>
<td>13.7</td>
<td>0.35</td>
</tr>
<tr>
<td>Stent thrombosis (def/prob) (%)</td>
<td>0</td>
<td>6.1</td>
<td>0.02</td>
</tr>
</tbody>
</table>
Conclusions

- During 5-year follow-up, routine T-stenting offered no advantage over provisional T-stenting with respect to TLR or MACE.

- Double stenting compared with single stenting was associated with an increased 5-year risk of stent thrombosis.