Bifurcation Lesion Intervention: Preferred Two Stent Strategy

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Disclosures
Bifurcation Stenting

- Bifurcation angioplasty accounts for 15% - 20% of total percutaneous coronary interventions

- PCIs in these circumstances challenging
  - Technically difficult and time consuming
  - Higher resource utilization and cost
  - Lower procedural success rates
  - Inferior angiographic and clinical outcomes

- Uncertainty about best treatment strategy
  - Lack of robust randomized data
  - Strategies based on the personal experiences
  - No two bifurcations are identical as variations in Anatomy and Dynamic changes during Intervention
Current classifications DO NOT help in procedural planning
Approach to Bifurcation Stenting: One or Two Stents
Dictated by Side Branch: Likely to occlude

No two bifurcations are identical

Require individualized approach?
Goal for performing bifurcation intervention is to optimize long term patency of main branch (MB), without compromising side branch (SB) patency.
Bifurcation Stenting: One Stent Strategy

- Provisional stenting performed in different ways
- Several technical refinements influence outcome

Following steps / technical tricks

- Wiring of both MB and SB
- Pre-dilatation of SB
- MB stent sized according to distal MB diameter
- Jailed Wire and Jailed balloon protection
- POT
- Rewiring of SB through distal strut of MB
- FFR of SB
- IVUS / OCT guidance
- FKB
- Stent selection
Bifurcation Stenting: One Stent Strategy

- Simple and easy technique

- Preferred if
  - SB small or clinically insignificant
  - SB large but with minimal disease

- Aim to
  - Optimize lumen dimensions in the MB
  - Keep Side Branch Open
    - Preserve physiologic flow in the SB
Bifurcation Stenting: Two Stent Strategy

- **Crossover:**
  5%-30%, patients assigned initially to a one-stent (provisional) approach require second stent due to **Suboptimal Result** in a large SB (> 2.5 mm)

- Plaque shift with >75% residual stenosis
- TIMI flow grade <3
- FFR<0.75
- Large SB dissection
- Persistent intra-procedural angina
- Electrocardiographic changes

- **Planned:**
  Two stent strategy for **Complex Lesions** as higher incidence of SB occlusion leading to haemodynamic compromise or peri-procedural MI

- SB have large diameters (>2.5 mm)
- Severe stenosis extending beyond the ostium (>10-20 mm)
- Unfavourable angle for re-crossing after MB stenting
Various Techniques for Stenting Bifurcation Lesions

**Bifurcation Lesion**

- Stent+PTCA
  - "V" - ≤ 5mm
- Stent+stent
  - "Kissing" "SKS"
- Stent+stent
  - "T stenting"
  - "reverse-T"
- Stent+stent
  - "Crush"
- Stent+stent
  - "Culotte"
**Indications**

- When angle between MB and SB wide (>70)
  - Although Crossing SB difficult but
    - Less Plaque shift
    - Better ostial coverage

**Advantages**

- Simple and technically less demanding

**Drawbacks**

- Small gap between stents
- Increased risk of SB ostial stenosis
T stenting largely replaced by TAP technique

- Simple and technically less demanding
- No gap between stents
- Less risk of SB ostial stenosis
- Few struts protruding in MB
Bifurcation Stenting: Crush Technique

Indications

- All true bifurcation
- When angle between MB and SB narrow (<70)

Advantages

- Complete coverage of SB ostium while ensuring patency of both branches throughout procedure

Drawbacks

- Excessive metal (3 layers) in MB can complicate rewiring and balloon re-crossing
Bifurcation Stenting: Crush Technique

Problems with Classic Crush:
- Excess metal in PMB
- Difficult to rewire/reballoon SB
- 7/8 Fr. Guide
- Cross over to 2 stents

Variants of Classic Crush:
- Mini Crush
- DK Crush
- Step Crush
- Reverse Crush
Bifurcation Stenting: Culotte Technique

Indications
- When SB large and MB and SB are of equal size

Advantages
- Provides the best coverage and least strut deformity at SB
- Angle between SB and MB does not constitute a problem

Drawbacks
- Technically demanding as requires rewiring of both stents
- One branch is unprotected during procedure
- SB stent malapposition to proximal MB stent when there is large discrepancy in diameter
- Excess metal at proximal MB and at carina.
Bifurcation Stenting: SKS and V Technique

Indications

- Proximal MB Should be 2/3rd of aggregate of two stents
- Angle between SB and MB narrow ( <70), 011 Medina

Advantages

- Access to MB and SB is always preserved with no need for rewiring any of the branches.
- Technically simple and easy

Drawbacks

- Creates a metallic neo carina
- Risk of proximal dissection & Asymmetric stent expansion
- If re-intervention is necessary rewiring may be challenging
Bifurcation Stenting: Summary of Techniques
SYNTAX: PCI Procedural Data
Bifurcation Subset: n= 1214
## Randomised Bifurcation Trials using DES Single Provisional vs 2 Stents Strategy

<table>
<thead>
<tr>
<th>Study (n = 1641)</th>
<th>No. of Pts</th>
<th>Duration</th>
<th>Primary End-Point</th>
<th>ONE STENT</th>
<th>TWO STENTS</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>NORDIC</td>
<td>413</td>
<td>6 mo</td>
<td>D, MI, TVR, ST</td>
<td>2.9</td>
<td>3.4</td>
<td>NS</td>
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<tr>
<td>CACTUS</td>
<td>350</td>
<td>6 mo</td>
<td>D, MI, TVR</td>
<td>15.0</td>
<td>15.8</td>
<td>NS</td>
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<tr>
<td>BBC ONE</td>
<td>500</td>
<td>9 mo</td>
<td>D, MI, TVF</td>
<td>8.0</td>
<td>15.2</td>
<td>0.009</td>
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<td>Ferenc et al BBK</td>
<td>202</td>
<td>9 mo</td>
<td>SB Ang. Restenosis</td>
<td>23.0</td>
<td>27.7</td>
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<tr>
<td>Colombo et al</td>
<td>85</td>
<td>6 mo</td>
<td>Angio Restenosis</td>
<td>18.7</td>
<td>28.0</td>
<td>NS</td>
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<tr>
<td>Pan et al</td>
<td>91</td>
<td>6 mo</td>
<td>Angio Restenosis</td>
<td>7.0</td>
<td>25.0</td>
<td>NS</td>
</tr>
</tbody>
</table>

Brar et al Euro Intervention 2009;5: 475
Randomised Trials using DES
Single Provisional vs 2 Stent Strategy

0.9% vs 0.8%  RR: 1.12

5.2% vs 5.9%  RR: 0.91

Brar et al Euro Intervention 2009;5: 475
Randomised Trials using DES
Single Provisional vs 2 Stent Strategy

<table>
<thead>
<tr>
<th>Study</th>
<th>Year</th>
<th>Events / Total</th>
<th>MH risk ratio and 95% CI</th>
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<tbody>
<tr>
<td>Two Provisional</td>
<td></td>
<td></td>
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<tr>
<td>Pan et al</td>
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<td>Colombo et al</td>
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<td>0.82</td>
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<tr>
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<td>0.33</td>
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<tr>
<td>Ferenc et al</td>
<td>2008</td>
<td>1/101</td>
<td>0.50</td>
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<tr>
<td>BBC ONE</td>
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<td>9/250</td>
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<tr>
<td>CACTUS</td>
<td>2009</td>
<td>15/173</td>
<td>0.81</td>
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<tr>
<td>Overall</td>
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<td>29/800</td>
<td>0.57</td>
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<tr>
<td>Overall</td>
<td></td>
<td>6/800</td>
<td>0.01</td>
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3.6% vs 6.7%  RR: 0.57  0.7% vs 1.6%  RR: 0.56

Brar et al Euro Intervention 2009;5: 475
5 Year Follow-Up: Simple vs Complex Stenting Strategy

BBK Study

Nordic Bifurcation Study and British Bifurcation Coronary Study

EurolInterv 2015

Behan et al. European Heart Journal 2016
Conservative strategy compared with Aggressive strategy for provisional SB intervention is associated with long-term benefits for patients with a large bifurcation lesion.
Randomized Comparisons Between Different Stenting Approaches for Bifurcation Coronary Lesions With or Without Side Branch Stenosis  

**MACE at 1 Year**
- 14.0% vs 11.6%
- 17.9% vs 18.5%
Randomized Comparison of Provisional Side Branch Stenting versus a Two-stent Strategy for treatment of True Coronary Bifurcation Lesions Involving a Large Side Branch.

**Primary End Point: MACE at 6 months**
Cardiac death, Non-procedural MI, TLR, Stent thrombosis

<table>
<thead>
<tr>
<th></th>
<th>Provisional (n=220)</th>
<th>Two-stent (n=227)</th>
<th>p</th>
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<tbody>
<tr>
<td>MACE</td>
<td>4.6</td>
<td>1.8</td>
<td>0.09</td>
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<tr>
<td>Cardiac Death (%)</td>
<td>0</td>
<td>0</td>
<td>-</td>
</tr>
<tr>
<td>Non-Procedural MI (%)</td>
<td>1.8</td>
<td>0.9</td>
<td>0.50</td>
</tr>
<tr>
<td>Stent Thrombosis (%)</td>
<td>0.9</td>
<td>0.4</td>
<td>0.54</td>
</tr>
<tr>
<td>TLR (%)</td>
<td>3.2</td>
<td>1.3</td>
<td>0.18</td>
</tr>
</tbody>
</table>

\[ p=0.09 \]

Survival free of MACE

- Provisional SB stent: 98.2%
- Two-stent: 95.4%

TCT, 2013
Two Stent techniques: DK Crush Stenting

DK CRUSH-1 STUDY
SIDE-BRANCH RESTENOSIS

- CRUSH NO Kiss: 36.6, p=0.001
- CRUSH KISS: 20.9, p=0.001
- DK CRUSH: 12.3

## Two Stent techniques: DKCRUSH III Trial

<table>
<thead>
<tr>
<th>Follow Up: 1 Year</th>
<th>DK crush (n=210)</th>
<th>Culotte (n=209)</th>
<th>p</th>
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</thead>
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<tr>
<td>Stent Thrombosis</td>
<td>0.5</td>
<td>1.0</td>
<td>0.623</td>
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<td>Restenosis</td>
<td>7.6</td>
<td>13.2</td>
<td>0.037</td>
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<tr>
<td>Composite MACE</td>
<td><strong>6.2</strong></td>
<td><strong>16.3</strong></td>
<td><strong>0.001</strong></td>
</tr>
<tr>
<td>Cardiac Death</td>
<td>1.0</td>
<td>1.0</td>
<td>1.000</td>
</tr>
<tr>
<td>MI</td>
<td>3.3</td>
<td>5.3</td>
<td>0.377</td>
</tr>
<tr>
<td>TVR</td>
<td>4.3</td>
<td>11.0</td>
<td>0.037</td>
</tr>
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</table>

DKCRUSH technique associated with less MACE, In-stent restenosis and TLR/TVR compared with Culotte technique

MACE at 3 Years: 8.2% vs 23.7% (p<0.001) JACC Inter 2015
Two Stent techniques: NORDIC II

n = 424

Traditional CRUSH vs CULOTTE

- No difference in clinical outcome at 6 months
- Limitations of study
  - Short FU period
  - Significantly less FKI in crush group

Primary End Point (MACE): 6 months

Crush 4.3%
Culotte 3.7%  
P=NS

Death, MI, TVR, Stent Thrombosis

Erglis A. Circ Cardiovasc interv 2009; 2:27
### Follow Up: 1 Year

<table>
<thead>
<tr>
<th></th>
<th>Crush (n=150)</th>
<th>Culotte (n=150)</th>
<th>p</th>
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<tbody>
<tr>
<td>Stent Thrombosis</td>
<td>2.7</td>
<td>1.3</td>
<td>0.68</td>
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<tr>
<td>Restenosis</td>
<td>12.7</td>
<td>6.0</td>
<td>0.047</td>
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<tr>
<td>Composite MACE</td>
<td>6.7</td>
<td>5.3</td>
<td>0.48</td>
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<tr>
<td>Cardiac Death</td>
<td>1.3</td>
<td>0.7</td>
<td>0.62</td>
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<tr>
<td>MI</td>
<td>4.7</td>
<td>2.0</td>
<td>0.33</td>
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<tr>
<td>TVR</td>
<td>6.0</td>
<td>4.7</td>
<td>0.60</td>
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</table>

**CRUSH technique associated with higher MACE, In-stent restenosis and TLR/TVR compared with Culotte technique**

Bifurcation Stenting: Crush vs SKS Technique

Sharma et al. Cardiol Clin 2006; 24:233

Stintis et al. Cath CVI 2010; 75:309
**Culotte versus T-stenting for Cross-over 2 stent Strategy in bifurcation lesions.** Kaplan et al. Am Heart J 2007

<table>
<thead>
<tr>
<th>Follow Up: 9 month</th>
<th>Culotte (n=45)</th>
<th>T stent (n=35)</th>
<th>p</th>
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<tr>
<td>Residual stenosis (SB)</td>
<td>3.44</td>
<td>12.55</td>
<td>0.001</td>
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<tr>
<td>Composite MACE</td>
<td>13.3</td>
<td>27.3</td>
<td>0.051</td>
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<tr>
<td>Stent Thrombosis</td>
<td>2.2</td>
<td>0</td>
<td>0.001</td>
</tr>
<tr>
<td>TLR</td>
<td>8.9</td>
<td>11.0</td>
<td>0.051</td>
</tr>
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</table>

Both techniques of provisional SB stenting in bifurcation lesions achieve high procedural success (100%) with low complication rates.

Culotte technique yields better angiographic result at SB ostium.
## Bifurcation Stenting: Two stent strategy

**Final Kissing Essential**

Hoye et al. JACC 2006; 47: 1947

<table>
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<tr>
<th></th>
<th>FKB N=163</th>
<th>No FKB N=14</th>
<th>P value</th>
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<tbody>
<tr>
<td><strong>Restenosis: MB</strong></td>
<td>6.0</td>
<td>12.0</td>
<td>0.2</td>
</tr>
<tr>
<td><strong>Restenosis: SB</strong></td>
<td>10.0</td>
<td>40.0</td>
<td>&lt; 0.0001</td>
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</table>

### CACTUS TRIAL

<table>
<thead>
<tr>
<th></th>
<th>FKB N=163</th>
<th>No FKB N=14</th>
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<td>12.9</td>
<td>0.25</td>
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<td><strong>Restenosis: MB</strong></td>
<td>4.7</td>
<td>16</td>
<td>0.03</td>
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<tr>
<td><strong>Restenosis: SB</strong></td>
<td>11.9</td>
<td>36</td>
<td>0.001</td>
</tr>
<tr>
<td><strong>ST</strong></td>
<td>0.9</td>
<td>6.5</td>
<td>0.06</td>
</tr>
</tbody>
</table>
Kim et al. analyzed a propensity-matched cohort comprising patients with non-left main bifurcation lesions that were treated under IVUS guidance \((n = 487)\) and under angiography guidance \((n = 487)\).

IVUS guidance was associated with larger maximal stent diameters in both the MB and SB, and lower cumulative incidences of Death or MI \((HR: 0.44; p = 0.04)\)
Bifurcation Stenting: Which Stent?

- DES Better than BMS
- Second / Third Generation Stents Better than First Generation Stents
- Will Fourth Generation (BRS) Prove Superior Not Yet Known
Bifurcation Stenting: Bioresorbable Stent (BRS)

- BRS might address limitations of conventional metallic DES in bifurcation PCI
- Provisional strategy default technique for bifurcation lesions using BRS
- 2 stent techniques- T, TAP, Hybrid

ADVANTAGES

- Lower stent thrombosis
- Lower restenosis, especially at SB ostium.
- Long-term jailing of SB may be avoided following BRS resorption in MB
- Long term benefits include restoration of endothelial function, positive vessel remodeling, and reduced risk for very late (stent) thrombosis

LIMITATIONS

- BVS are bulky which may hinder device delivery in a bifurcation lesion
- Thick struts more thrombogenic than thinner struts
- Less Radial strength of BRS puts restrictions on postdilatation-POT, FKBD
- Mini-KBPD or snuggle balloon dilatation recommended
Bifurcation Stenting: BRS

Hybrid Mini-Crush Technique

Elective T Stenting
Bifurcation Stenting: Bioresorbable Stent (BRS)

Bioresorbable Vascular Scaffold for Treatment of Coronary Bifurcation Lesions
Lezo et al. Revista Espanola de Cardiologia, 2016

- 194 patients with 230 bifurcation lesions treated with BRS in a single center
- Successful in All
- Clinical Follow-Up: 14 months

<table>
<thead>
<tr>
<th>Event</th>
<th>Count</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>TLR/restenosis:</td>
<td>12</td>
<td>(5.6%)</td>
</tr>
<tr>
<td>Stent thrombosis:</td>
<td>2</td>
<td>(1.3%)</td>
</tr>
<tr>
<td>MACE:</td>
<td>18</td>
<td>(8.7%)</td>
</tr>
</tbody>
</table>

- Provisional 1 Stent Strategy: (222 lesions)
  - Postdilated SB in 40%
  - Crossover to 2 stents in 3 (T stent)

- 2 Stent Strategy: (8 lesions)
  - T stenting: 4
  - V stenting: 2
  - Culotte stenting: 2

Clinical outcomes following bioresorbable scaffold for bifurcation lesions

N=122. FU: 1 year

BRS in bifurcation lesions

Provisional stenting (99 lesions) vs Planned 2 stent (23 lesions)

<table>
<thead>
<tr>
<th>Event</th>
<th>Rate</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>MACE:</td>
<td>9.5%</td>
<td>0.91</td>
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<tr>
<td>TLR:</td>
<td>5.5%</td>
<td>0.49</td>
</tr>
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</table>
Bifurcation Stenting: Dedicated Bifurcation Devices

1. MB stenting with some degree of SB scaffolding (provisional SB stenting)

2. Side branch stents

3. Proximal Stent

4. Bifurcated stent

Majority of devices aimed at facilitating MB Stenting while preserving a safe access to SB.
The Tryton Bifurcation Trial: A randomized comparison of a provisional one-stent vs. a dedicated two-stent strategy for true bifurcation coronary lesions TCT 2013

- Tryton two-stent strategy in true bifurcations compared with provisional strategy did not meet non-inferiority clinical endpoint (TVF), due to a relatively higher frequency of small peri-procedural MI

Both strategies were safe (rare clinically significant MIs and stent thrombosis) and both had low 9-month clinically-driven TVR

DES in the main vessel performed well in both arms

Tryton improved side branch % diameter stenosis at FU
COBRA Trial: COmplex coronary Bifurcation lesions: RAndomized comparison of a strategy using a dedicated self-expanding biolimus-eluting stent versus a culotte strategy using everolimus-eluting stents

Axxess™ bifurcation stent in proximal main vessel (MV) and BioMatrix™ stents in branches vs Culotte technique using XIENCE™ stents in 40 patients with true bifurcation lesions

**Percentage of uncovered struts at nine months was similar**

- Proximal MV (17.8 vs. 6.8; p=0.19)
- Distal MV (2.6 vs. 2.2; p=0.09)
- Bifurcation Core (9.5 vs. 4.0; p=0.17)
- Side Branch (5.7 vs. 1.9; p=0.14)

Axxess resulted in significantly larger lumen in proximal MV

Lower angiographic late lumen loss with Axxess stent

No Stent thrombosis in both strategies

Both strategies resulted in good clinical outcomes at one yr
Bifurcation Stenting: Conclusions

- “Single MB Stent with Provisional SB Stent” remains the strategy of choice for majority *(Stents do not like Bends)*

- Techniques of choice:
  - DK Crush and Culotte for two stent strategy
  - TAP for provisional stenting

- When 2 stents are required – No Penalty, if results Optimal

- Dedicated Bifurcated Stents / BRS need more refinements

- FFR, OCT, IVUS help understanding complexities

- More attention should be paid to optimising the chosen technique than to choosing among techniques
Bifurcation Stenting: Conclusions

- Plan Your Strategy
- Have Back Up Plan: B, C even D
- Best is enemy of Good
- Keep It Simple, Swift and Safe (KISSS)

Thank You