Bifurcation Analysis

Progress Report and validation of bifurcation QCA by Medis

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Coronary Casts: Understanding Ostial Geometry
Oval and Asymmetric Rather than Round

courtesy of Mary Russel, MD, PhD

Example: Side Branch of RCA

Sketches of ostium
conical taper
elliptical
Understanding Ostial geometry: Transition Zone Taper Greater by 3-fold

Courtesy of Mary Russel, MD, PhD

Example of Diameter Measurements

<table>
<thead>
<tr>
<th>At 3 mm</th>
<th>At 6 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proximal diameter</td>
<td>3.14</td>
</tr>
<tr>
<td>Distal diameter</td>
<td>2.44</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>At ostium</th>
<th>At 3 mm</th>
<th>At 6 mm</th>
</tr>
</thead>
<tbody>
<tr>
<td>Side branch diameter</td>
<td>2.50</td>
<td>1.96</td>
</tr>
</tbody>
</table>

Average Taper

- **Vessels with SB > 1.65 mm**
  - Proximal to Distal Taper (Main Vessel): 0.09 mm
  - Ostium to Side Branch Taper (Side Branch): 0.30 mm

Main Vessel Tapers 0.56 mm over 6.00 mm distance

Side Branch Tapers 0.53 mm over 1.75 mm distance
Approach to the bifurcation

The analysis consists of

- Proximal parent vessel
- Bifurcation Core
- Distal parent vessel
- Side branch

Bifurcation Core sizing should be independent of presence of disease

Assumes carina point it is not diseased
Different bifurcation anatomies: Different model depending on vessel structure, device and intervention strategy

Y-shaped analysis suitable for:
- Bifurcations with distal branches of equal size
- Left Main Bifurcation
- Bifurcations with narrow angle b/w distal branches
- Analysis of skirt /carinal stents
- Analysis of stents with both distal branch stents

T-shaped analysis suitable for:
- Bifurcations of standard ‘sidebranch’ structure
- Side branch diameter less than PV
- Bifurcations with wide angle b/w distal branches
Y-shaped analysis

Y-shaped approach for bifurcations with equally important distal branches

Pre

Final
Solution for reference contours

- Use a proprietary algorithm to create reference contours of the bifurcation core
- Assumes carinal point is not diseased: Both arterial and reference contours go through the carina point
Y-shaped analysis II

- 3 diameter functions:
  - One for the proximal branch including the bifurcation core
  - One for each distal branch, starting distal to the carina
Clinical example Y-shaped model
T-shaped analysis

Typical approach for standard ‘sidebranch’ structure
T-shaped analysis II

- Two diameter functions
  - One for the proximal branch and the main distal branch including the bifurcation core
  - Allowing for 2 obstruction to match Medina Class
    - One for the side branch
Clinical example T-shaped model
Bifurcation Edge Segment Analysis

1 – Edge PPV
2 – Stent PPV
3 – Stent DPV*
4 – Edge DPV*
5 – Stent SB*
6 – Edge SB*

*If Placed

7 – Ostium DPV (3 or 5 mm)
8 – Ostium SB (3 or 5mm)
9 – Analyzed PPV
10 – Analyzed DPV*
11 – Analyzed SB*

*If Placed

Default available segments
A – Proximal Parent Vessel = PPV
B – Bifurcation Core
C – Distal Parent Vessel = DPV
D – Side Branch = SB

Proximal Parent Vessel
Side Branch
Distal Parent Vessel
Case Example: DEVAX Stent

- Self expanding
- Nickel-titanium (Nitinol) alloy
- Conical shape
- Diameters 2.5, 3.0, or 3.5mm
- Lengths 10, 14, or 20mm
- Biolimus A9
- Polymer: PLA
**Results of Y-shaped analysis**

Preliminary data of Devax stent study

<table>
<thead>
<tr>
<th>Acute gain (n=10)</th>
<th>Prox. Parent Vessel incl. Bifurcation Core</th>
<th>Dist. Parent Vessel</th>
<th>Side Branch</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obs D (mm)</td>
<td>1.73</td>
<td>0.84</td>
<td>0.29</td>
</tr>
<tr>
<td>Ref D (mm)</td>
<td>-0.20</td>
<td>0.17</td>
<td>-0.02</td>
</tr>
<tr>
<td>%D Stenosis</td>
<td>-52.4</td>
<td>-28.2</td>
<td>-12.4</td>
</tr>
<tr>
<td>Obs Length (mm)</td>
<td>-2.7</td>
<td>-2.0</td>
<td>0.0</td>
</tr>
</tbody>
</table>
Validation Study:
TriReme Medical TOP study

• Goal of study
  – 60 pt EU safety and feasibility study
  – MB stenting with SB preservation
  – Struts in first 2 mm of sidebranch

• First 9 patient cases, repeated pre- and post intervention analyses

• Device ideal for T-shape analysis
TriReme: Design features tailored to Ostial geometry and dimensions

Stent geometry
Ostial Scaffolding
Asymmetric Design
Obtuse superior angle
Acute inferior angle

Material
316L stainless steel

Positioning
6F torqueable catheter

Strut thickness
0.0035”

Crimped profile
0.046”/0.038”

Available sizes
3.0-4.5 mm PV
2.0-3.5 mm SB

Automatic deployment of ostial crown upon expansion of main stent body
– single balloon use –ostial markers provide support, alignment –minimize injury
### Intra-Observer Results of T-shaped analysis

<table>
<thead>
<tr>
<th>Pre- and Post-intervention (n=18)</th>
<th>Prox. Parent Vessel incl. Bifurcation Core</th>
<th>Dist. Parent Vessel</th>
<th>Side Branch</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obs D (mm)</td>
<td>0.01 ± 0.03</td>
<td>-0.01 ± 0.04</td>
<td>0.01 ± 0.05</td>
</tr>
<tr>
<td>Ref D (mm)</td>
<td>0.08 ± 0.10</td>
<td>0.01 ± 0.08</td>
<td>0.04 ± 0.10</td>
</tr>
<tr>
<td>%D Stenosis</td>
<td>0.8 ± 1.7</td>
<td>0.5 ± 2.0</td>
<td>0.5 ± 3.0</td>
</tr>
<tr>
<td>Obs Length (mm)</td>
<td>0.7 ± 1.2</td>
<td>-0.1 ± 1.0</td>
<td>0.4 ± 1.2</td>
</tr>
</tbody>
</table>

All results expressed as mean difference ± standard deviation.
### Intra-Observer Results of Y-shaped analysis

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<th>Pre- and Post-intervention (n=18)</th>
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<tbody>
<tr>
<td>Obs D (mm)</td>
<td>0.00 ± 0.03</td>
<td>0.02 ± 0.08</td>
<td>-0.01 ± 0.06</td>
</tr>
<tr>
<td>Ref D (mm)</td>
<td>0.03 ± 0.11</td>
<td>-0.03 ± 0.09</td>
<td>0.02 ± 0.10</td>
</tr>
<tr>
<td>%D Stenosis</td>
<td>0.5 ± 1.7</td>
<td>-1.8 ± 3.7</td>
<td>1.3 ± 4.5</td>
</tr>
<tr>
<td>Obs Length (mm)</td>
<td>0.0 ± 1.4</td>
<td>-0.4 ± 1.0</td>
<td>-0.5 ± 4.0</td>
</tr>
</tbody>
</table>

All results expressed as mean difference ± standard deviation.
## Results of T-shaped analysis

Preliminary data of TriReme stent study

<table>
<thead>
<tr>
<th>Acute gain (n=9)</th>
<th>Prox. Parent Vessel incl. Bifurcation Core</th>
<th>Dist. Parent Vessel</th>
<th>Side Branch</th>
</tr>
</thead>
<tbody>
<tr>
<td>Obs D (mm)</td>
<td>1.60</td>
<td>0.84</td>
<td>0.85</td>
</tr>
<tr>
<td>Ref D (mm)</td>
<td>0.28</td>
<td>-0.04</td>
<td>0.10</td>
</tr>
<tr>
<td>%D Stenosis</td>
<td>-45.0</td>
<td>-35.8</td>
<td>-36.0</td>
</tr>
<tr>
<td>Obs Length (mm)</td>
<td>-3.2</td>
<td>-1.5</td>
<td>-1.3</td>
</tr>
</tbody>
</table>
## Edge Segment Definitions

<table>
<thead>
<tr>
<th>Position</th>
<th>Length</th>
<th>MLD</th>
<th>MLD Ref D</th>
<th>% DS</th>
<th>Distance</th>
<th>Max D</th>
<th>Mean D</th>
</tr>
</thead>
<tbody>
<tr>
<td>Segment 1</td>
<td>5.00</td>
<td>0.523</td>
<td>3.843</td>
<td>3.728</td>
<td>-3.07</td>
<td>0.174</td>
<td>3.845</td>
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<tr>
<td>Segment 3</td>
<td>6.53</td>
<td>25.724</td>
<td>2.560</td>
<td>2.462</td>
<td>-3.96</td>
<td>1.761</td>
<td>2.380</td>
</tr>
<tr>
<td>Segment 4</td>
<td>5.00</td>
<td>27.485</td>
<td>2.229</td>
<td>2.443</td>
<td>8.76</td>
<td>2.560</td>
<td>2.380</td>
</tr>
<tr>
<td>Segment 5</td>
<td>10.63</td>
<td>19.253</td>
<td>1.786</td>
<td>2.368</td>
<td>24.57</td>
<td>5.400</td>
<td>2.160</td>
</tr>
<tr>
<td>Segment 6</td>
<td>5.00</td>
<td>30.012</td>
<td>1.685</td>
<td>1.944</td>
<td>13.31</td>
<td>1.056</td>
<td>1.815</td>
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<tr>
<td>Segment 7</td>
<td>5.00</td>
<td>24.198</td>
<td>2.876</td>
<td>2.478</td>
<td>-16.04</td>
<td>3.231</td>
<td>3.049</td>
</tr>
<tr>
<td>Segment 8</td>
<td>5.00</td>
<td>19.253</td>
<td>1.786</td>
<td>2.368</td>
<td>24.57</td>
<td>5.400</td>
<td>2.158</td>
</tr>
<tr>
<td>Segment 10</td>
<td>11.53</td>
<td>27.485</td>
<td>2.229</td>
<td>2.443</td>
<td>8.76</td>
<td>3.231</td>
<td>2.717</td>
</tr>
<tr>
<td>Segment 11</td>
<td>15.63</td>
<td>19.253</td>
<td>1.786</td>
<td>2.368</td>
<td>24.57</td>
<td>5.400</td>
<td>2.050</td>
</tr>
</tbody>
</table>
Conclusions

- Highly accurate and precise arterial and reference contour measures (including bifurcation core measures)
- No evidence of systematic error (especially in the bifurcation core)
- Solution for all shapes of bifurcations and types of intervention
Interventional Rounds

Quantitative Angiographic Methods for Bifurcation Lesions: A Consensus Statement from the European Bifurcation Group

Alexandra Lansky,1* Joan Tuinenburg,2 Marco Costa,3 Micheal Maeng,4 Gerhard Koning,2 Jeffrey Popma,5 Ecatarina Cristea,1 Laurence Gavit,6 Ricardo Costa,7 Andrei Rares,2 Gerritt-Ann Van Es,8 Thierry Lefevre,9 Hans Reiber,2 Yves Louvard,9 and Marie-Claude Morice9 on behalf of the European Bifurcation Angiographic Sub-Committee

The treatment of bifurcation lesions is complex and increasingly common. A growing number of dedicated bifurcation devices are under clinical evaluation, but no standardized methodology exists. Specifically, the angiographic analysis of bifurcation lesions is not standardized and current QCA packages are not designed for bifurcation lesions. This consensus statement outlines the limitations of conventional QCA in the bifurcation application, and outlines a new standard approach for the analysis and reporting of the angiographic results of the bifurcation lesion allowing for future trial and device comparisons and mechanistic insight into location and modes of treatment failure.

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Key words: quantitative coronary angiography; diagnostic cardiac catheterization; percutaneous coronary intervention

INTRODUCTION

The angiographic analysis of bifurcation lesions presents a considerable dilemma, as there is currently no standard methodology and the available quantitative angiographic software packages (for straight vessel treatment) are not designed to address the unique...