Importance of Stent Shape and Area On Clinical Outcomes after VICI Stent Trial

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Take Home

- Area is important, but...
  - For a Given Perimeter:
    - Larger shape impacts area
    - Lumen shape impacts flow and pressure
    - Aspect Ratio is a better predictor of stent performance and patient outcomes

Stent Strength

- Chronic Occlusion
- Crash Resistance
- Radio Resistance

Calculating Area of Shapes with Same Perimeter

<table>
<thead>
<tr>
<th>Shape</th>
<th>Perimeter (P)</th>
<th>Aspect Ratio (AR)</th>
<th>Area (A)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Circle</td>
<td>44 mm</td>
<td>1</td>
<td>154 sq mm</td>
</tr>
<tr>
<td>Ellipse</td>
<td>43 mm</td>
<td>2</td>
<td>127 sq mm</td>
</tr>
<tr>
<td>Ellipse</td>
<td>43 mm</td>
<td>4</td>
<td>79 sq mm</td>
</tr>
</tbody>
</table>

Area Decreases as Shape becomes Flatter

Relationship of Area and Shape, Pressure and Flow

- Larger changes in flow are related to small systemic pressure changes
- Decreasing transmural pressure has little impact on flow
- As shape becomes flatter, flow increases and pressure and turbulence increase
- Flatter vessels have less resistance and better flow

Disclosure

Lowell S. Kabnick, MD, RPhS, FACS, FACPh:

- I have no conflicts
How do we measure Aspect Ratio?
The Degree of Roundness

Aspect Ratio
Max Diameter to Min Diameter

Round 1 2 4
Oval

Changes in Aspect Ratio: Impact on Area, Flow and Pressure (Holding Perimeter Constant)

Pressure increases peripherally

Increasing Flatness
Round = more area and less drag thus better flow
Round = more area and less drag thus better flow

Increasing flatness = less area and more drag thus less flow

2015 Publication Demonstrates that: Better Patency Associated with Rounder Lumen

- All patients with stent compression at crossing of iliac artery at ilio-caval crossing.
- Follow-up performed with CT angiography.
- Stent compression remained unchanged in all cases.
- Aspirin resistance 95%, Shape Ratio 1.2
- Significant stent compression was noted compared with aspirin group (p < 0.01)

Does Shape Result in Better Patient Outcomes?

- Healthy values are highly compliant and change shape dynamically with pressure and flow change.
- VIRTUS Study - Feasibility and Pilot Cohorts - Provides a basis for patient trajectory positives and outcomes.
- In-vitro study performed using vessel segment, predictor of patient outcomes?

VIRTUS IDE Study: Feasibility Cohort

<table>
<thead>
<tr>
<th>Patient demographics, n = 30</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>24 (80%)</td>
</tr>
<tr>
<td>Age</td>
<td>63 (18-95)</td>
</tr>
<tr>
<td>0</td>
<td>1 (5%)</td>
</tr>
<tr>
<td>1</td>
<td>10 (33%)</td>
</tr>
<tr>
<td>2</td>
<td>11 (37%)</td>
</tr>
<tr>
<td>3</td>
<td>2 (6%)</td>
</tr>
<tr>
<td>4</td>
<td>1 (3%)</td>
</tr>
<tr>
<td>5</td>
<td>5 (16%)</td>
</tr>
<tr>
<td>Limb</td>
<td>26 (87%)</td>
</tr>
<tr>
<td>Average</td>
<td>70 (20-92%)</td>
</tr>
</tbody>
</table>

A Deeper Dive into the VIRTUS Feasibility Cohort: Early Look at Lumen Shape and 12-month Patient Outcomes

Aspect Ratio = Maximum Diameter (Major Axis) / Minimum Diameter (Minor Axis)
Statistical Analysis Design

- Correlation coefficient (r) measured the strength of the relationship between the following pairs of variables:
  - Post-stent change in VCSS and changes in 12-month VCSS
  - Post-stent change in aspect ratio and changes in 12-month VCSS

Interpretation of correlation coefficients are per the following thresholds:

* -1 = Perfect negative (i.e., downhill) linear relationship
-0.70 = Strong negative relationship
-0.50 = Moderate negative relationship
-0.30 = Weak negative relationship
0 = No relationship
0.3 = Weak positive relationship
0.5 = Moderate positive relationship
0.7 = Strong positive relationship
1.0 = Perfect positive relationship

Anatomic Measurements in Feasibility Cohort Before and After Stenting (median measurements N=27)

<table>
<thead>
<tr>
<th>Median</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre Stent</td>
</tr>
<tr>
<td>Area, cm^2</td>
</tr>
<tr>
<td>Aspect Ratio</td>
</tr>
</tbody>
</table>

**Significantly Rounder Shape**

**Increased Area**

**AREA IS IMPORTANT!**

**HOWEVER THE QUESTION IS WHETHER ASPECT RATIO IS A BETTER PREDICTOR OF PATIENT OUTCOMES**

VCSS – Our Metric to Assess 12-month Patient Outcome

| VCSS Score Pre-Stent & Post-Stent & 12 months Pre-Stent Post-Stent 12 months |
|----------------------------------------|-----------------|-----------------|-----------------|
| Pre-Stent VCSS score, n = 30 | 9 (2-25) | 12-month VCSS score, n = 27 | 4 (0-23) |
| No. with 50% score improvement | 17 (63%) | No. with ≥2 point improvement | 23 (85%) |
| No. with no score improvement | 25 (83%) | No. with score change | 2 (7%) |
| No. with score worsening | 21 (74%) | Mean VCSS change (Pre-stent to 12 months) | 5 (2-14) |
| * Three subjects outside follow-up window 365 +/- 60 days |

**VCSS – Our Metric to Assess 12-month Patient Outcome**

Data Analysis

Pre-Stent, Post-Stent and 12 month Changes in Aspect Ratio and Area were Performed

<table>
<thead>
<tr>
<th>Aspect Ratio (Max Dia / Min Dia)</th>
<th>Area</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Stent</td>
<td>Post-Stent</td>
</tr>
<tr>
<td>2.51</td>
<td>1.33</td>
</tr>
</tbody>
</table>

**Significantly Rounder Shape**

**Increased Area**

In Conclusion

- One would expect a positive correlation between area change and clinical improvement, but not observed
- Looking at the graphs - No clear pattern for area change, while change in Aspect Ratio is clearer
- Moderately positive relationship between decreased ellipticity and clinical improvement
- Patients with greatest luminal change – oval to round – Most likely to exhibit clinical improvement
- Changes in post-stent vessel shape may be more important than area
- Rounder post-stent lumen shape has positive correlation to 12-month patient improvement (VCSS)
- Stent design important + High crush resistance
TAKE HOME

KEY POINTS

For a Given Perimeter...

• Lumen shape impacts area
• Lumen shape impacts pressure
• Aspect Ratio is a better predictor of flow and patient outcomes versus Area

Healthy Veins are not Round: What Shape Results in Better Patient Outcomes?

Healthy veins are highly compliant and change shape dynamically when pressure and flow change.

Early clinical evidence (VIRTUS Feasibility Data) suggests that post-stenting—a rounder lumen may result in better VCSS outcomes at 1 year.

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