New Horizons for IR

James Benenati MD

Miami Cardiac & Vascular Institute
BAPTIST HEALTH SOUTH FLORIDA
Freeze it
Subintimally dissect it
Stent it
Balloon it
Excise it
Laser it
Remote it
PAD
Sand it!!!
Drug it
Freeze it
Graft it

Miami Cardiac & Vascular Institute
BAPTIST HEALTH SOUTH FLORIDA
Uterine Fibroid Embolization

Publications and trials began in 1997
Now standard practice in USA
Participation in CREST and numerous other industry and FDA sponsored trials
Publications leading to FDA approval of optional filters
Publication on treatment of visceral artery aneurysms with one of the largest series reported

Miami Cardiac & Vascular Institute
BAPTIST HEALTH SOUTH FLORIDA
Publication on treatment of visceral artery aneurysms with one of the largest series reported
Snorkel graft

- Parallel graft alongside the main aortic endoprosthesis to maintain flow in a covered branch vessel.
Fenestrations and scallops
Proglide Perclose
Left Brachiocephalic Vein
Thoracic Aorta
Sideclamped Ascending Aorta (asterisk)
MRI Guided Drug Delivery

- Plan Treatment
- MRI Monitor
- Heat
- HIFU
- LTSL
- Deliver desired dose
- Dose painting – spatio-temporal
Molecular Imaging in Atherosclerosis

Leuschner and Nahrendorf, Circ Res 2011
Term Maps: 1998-2002

1) proximity of terms on the map reflects their increased co-occurrence in titles and abstracts: e.g. “chemoembolization” and “hepatocellular carcinoma” travel together, as do “stent” and “primary patency rate”; 2) the size of the node indicates the number of occurrences of the words: e.g. “vein” is much larger than “matrix metalloproteinase”; and 3) their color shows number of citations.
<table>
<thead>
<tr>
<th>Procedure</th>
<th>2005</th>
<th>2011</th>
<th>Change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coronary Artery Stent or Angioplasty</td>
<td>465,000</td>
<td>373,000</td>
<td>-20%</td>
</tr>
<tr>
<td>Lower Extremity Arterial Angioplasty</td>
<td>105,000</td>
<td>175,000</td>
<td>67%</td>
</tr>
<tr>
<td>Renal Artery Angioplasty</td>
<td>21,000</td>
<td>8,000</td>
<td>-62%</td>
</tr>
<tr>
<td>Endovascular Aortic Aneurysm Repair</td>
<td>29,000</td>
<td>33,000</td>
<td>14%</td>
</tr>
<tr>
<td>Carotid Stent</td>
<td>13,000</td>
<td>12,000</td>
<td>-8%</td>
</tr>
<tr>
<td>Thoracic Aortic Aneurysm Repair</td>
<td>N/A</td>
<td>4,000</td>
<td>N/A</td>
</tr>
<tr>
<td>Venous Ablation (RF or Laser)</td>
<td>25,000</td>
<td>125,000</td>
<td>400%</td>
</tr>
<tr>
<td>Venous Angioplasty</td>
<td>187,000</td>
<td>303,000</td>
<td>62%</td>
</tr>
<tr>
<td>Transcatheter Embolization</td>
<td>23,000</td>
<td>35,000</td>
<td>52%</td>
</tr>
<tr>
<td>Mechanical Thrombectomy</td>
<td>N/A</td>
<td>8,000</td>
<td>N/A</td>
</tr>
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</table>
Some Specifics
Zilver PTX Study Design

Primary Randomization

- PTA
- Zilver PTX

Secondary Randomization

- Suboptimal PTA
- Optimal PTA
- Provisional BMS
- Provisional Zilver PTX

Enrollment
## Patient Demographics and Comorbidities

<table>
<thead>
<tr>
<th></th>
<th>PTA</th>
<th>Zilver PTX</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients</td>
<td>238</td>
<td>236</td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td>68 ± 11</td>
<td>68 ± 10</td>
<td>0.88</td>
</tr>
<tr>
<td>Male</td>
<td>64%</td>
<td>66%</td>
<td>0.70</td>
</tr>
<tr>
<td>Height (in)</td>
<td>66 ± 4</td>
<td>67 ± 4</td>
<td>0.55</td>
</tr>
<tr>
<td>Weight (lbs)</td>
<td>179 ± 44</td>
<td>180 ± 40</td>
<td>0.62</td>
</tr>
<tr>
<td>Diabetes</td>
<td>42%</td>
<td>50%</td>
<td>0.11</td>
</tr>
<tr>
<td>High cholesterol</td>
<td>70%</td>
<td>76%</td>
<td>0.12</td>
</tr>
<tr>
<td>Hypertension</td>
<td>82%</td>
<td>89%</td>
<td>0.02*</td>
</tr>
<tr>
<td>Past/current smoker</td>
<td>84%</td>
<td>86%</td>
<td>0.70</td>
</tr>
</tbody>
</table>

* Statistically significant
## Baseline Lesion Characteristics

<table>
<thead>
<tr>
<th></th>
<th>PTA</th>
<th>Zilver PTX</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesions</td>
<td>251</td>
<td>247</td>
<td></td>
</tr>
<tr>
<td>Normal-to-normal lesion length (mm)</td>
<td>63 ± 41</td>
<td>66 ± 39</td>
<td>0.36</td>
</tr>
<tr>
<td>Stenosed lesion length (mm)$^{1,2}$</td>
<td>53 ± 40</td>
<td>55 ± 41</td>
<td>0.71</td>
</tr>
<tr>
<td>Diameter stenosis (%)$^1$</td>
<td>78 ± 17</td>
<td>80 ± 17</td>
<td>0.38</td>
</tr>
<tr>
<td>Total occlusions</td>
<td>27%</td>
<td>33%</td>
<td>0.20</td>
</tr>
<tr>
<td>De novo lesions</td>
<td>94%</td>
<td>95%</td>
<td>0.68</td>
</tr>
<tr>
<td>Lesion calcification$^1$</td>
<td>None</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>5%</td>
<td>2%</td>
<td></td>
</tr>
<tr>
<td>Little</td>
<td>38%</td>
<td>26%</td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>22%</td>
<td>35%</td>
<td></td>
</tr>
<tr>
<td>Severe</td>
<td>35%</td>
<td>37%</td>
<td></td>
</tr>
</tbody>
</table>

$^1$ Angiographic core lab assessment

$^2$ Region with > 20% diameter stenosis

* Statistically significant
Outline

- Study design and baseline characteristics
- Safety results through 5 years
  - Stent integrity
- Effectiveness results through 5 years
  - Zilver PTX vs. standard care
  - Provisional Zilver PTX vs. Provisional BMS
- Conclusions
5-year Stent Integrity

<table>
<thead>
<tr>
<th>Study Period</th>
<th>Number of New Events</th>
<th>Fracture Rate$^1$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrollment</td>
<td>0</td>
<td>0.0%</td>
</tr>
<tr>
<td>1-year</td>
<td>4</td>
<td>0.9%</td>
</tr>
<tr>
<td>3-year</td>
<td>3</td>
<td>1.9%</td>
</tr>
<tr>
<td>5-year</td>
<td>0</td>
<td>1.9%</td>
</tr>
</tbody>
</table>

$^1$ Kaplan-Meier estimates

Zilver PTX has excellent durability in challenging SFA environment
Outline

- Study design and baseline characteristics
- Safety results through 5 years
  - Stent integrity
- Effectiveness results through 5 years
  - Zilver PTX vs. standard care
  - Provisional Zilver PTX vs. Provisional BMS
- Conclusions
At 5 years, Zilver PTX demonstrates a 48% reduction in reintervention compared to standard care.
At 5 years, Zilver PTX demonstrates a 41% reduction in restenosis compared to standard care.

<table>
<thead>
<tr>
<th>Years (LESIONS)</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zilver PTX</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>At Risk</td>
<td>318</td>
<td>246</td>
<td>199</td>
<td>163</td>
<td>137</td>
<td>109</td>
</tr>
<tr>
<td>Failed</td>
<td>1</td>
<td>48</td>
<td>71</td>
<td>83</td>
<td>92</td>
<td>94</td>
</tr>
<tr>
<td>Standard Care</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>At Risk</td>
<td>183</td>
<td>108</td>
<td>64</td>
<td>52</td>
<td>44</td>
<td>38</td>
</tr>
<tr>
<td>Failed</td>
<td>0</td>
<td>57</td>
<td>73</td>
<td>79</td>
<td>84</td>
<td>86</td>
</tr>
</tbody>
</table>

66.4% Zilver PTX
43.4% Optimal PTA + BMS

p < 0.01 log-rank
5-year Primary Patency (PSVR < 2.0)

Zilver PTX vs. Standard Care

From 1-5 years, the relative separation increases by 35%
At 5 years, Zilver PTX has a superior rate of freedom from persistent or worsening claudication, rest pain, ulcer, or tissue loss.

**5-year Clinical Benefit Index**

**Zilver PTX vs. Standard Care**

Zilver PTX

Optimal PTA + BMS

79.8%

59.3%

\[ p < 0.01 \]

\[ \log\text{-rank} \]
At 5 years, Zilver PTX demonstrates a 47% reduction in reintervention compared to BMS.

5-year Freedom from TLR
Provisional Zilver PTX vs. BMS

84.9%
Provisional Zilver PTX

71.6%
Provisional BMS

p = 0.06 log-rank

At 5 years, Zilver PTX demonstrates a 47% reduction in reintervention compared to BMS.
At 5 years, Zilver PTX has a superior rate of freedom from persistent or worsening claudication, rest pain, ulcer, or tissue loss.
Conclusions for 5-year Zilver PTX RCT

- As the first randomized controlled SFA device trial with 5-year follow-up, these results with the Zilver PTX stent provide important insights regarding long-term outcomes for endovascular treatment.

- 5-year data for Zilver PTX versus standard care:
  - Greater than 40% reduction in reintervention and restenosis
  - Superior clinical benefit
  - These benefits increase with time – results with Zilver PTX continue to diverge from standard care over 5 years with no late catch-up

- 5-year results confirm long-term superiority of Zilver PTX versus bare metal stents

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BAPTIST HEALTH SOUTH FLORIDA
CC: severe right calf pain when walking

- **Hx:** 64 M former smoker with diabetes, HTN presents with 6-month **severe, life-style limiting right calf claudication (Rutherford III)**. Progressed from 100-200 yards to 50-100 feet starting 2 weeks ago.

- **PMH:**
  - Prior mid to distal R SFA stents, 2012
  - Subsequent R fem-pop bypass, 2012 – right asymptomatic until 6 months ago
  - Cardiac risk factors: diabetes, HTN, former smoker (quit 2.5 years ago; 50+ pack-year hx)

- **Pertinent Meds:** ASA 81mg qday, Coumadin
Exam/Labs:

- **Physical Exam:**
  - Right foot and toes asymmetrically cold, dusky without ulceration or skin breakdown
  - Pulse Exam:

<table>
<thead>
<tr>
<th>Artery</th>
<th>Right</th>
<th>Left</th>
</tr>
</thead>
<tbody>
<tr>
<td>Femoral</td>
<td>2+</td>
<td>2+</td>
</tr>
<tr>
<td>Popliteal</td>
<td>NP</td>
<td>NP</td>
</tr>
<tr>
<td>Dorsalis Pedis a.</td>
<td>ND</td>
<td>D2</td>
</tr>
<tr>
<td>Post tibialis a.</td>
<td>ND</td>
<td>D2</td>
</tr>
</tbody>
</table>

- **Labs:** CBC wnl; Cr: 1.28 (GFR 57), INR 1.6 (stopped Coumadin 4 days prior)
Arterial LE
Non-invasive
Left CFA retrograde access
Run-off of Right lower extremity
(via 6 Fr Destination sheath terminating in R EIA)

R prox thigh

R dist thigh

R tibioperoneal
Plan: Recanalize long-segment SFA occlusion including occluded stents
Antegrade recanalization
(4-Fr Quickcross + 035 Glidewire)

Initially select occluded fem-pop bypass graft

Subsequently select occluded SFA
Despite multiple attempts, could not recanalize occluded stent
Retrograde access of occluded R SFA stent
(Thigh everted; re-prepped; fluoro-guided access with Micropuncture needle + 018 Nitrex wire)
Upsized to 035 system: micropuncture sheath → 035 Glidewire + 4-Fr Glide Cobra catheter
Attempted to get intraluminal
Snared Glidewire from L CFA access; through-and-through access with Exchange-Length Super Stiff Amplatz
From L CFA up-and-over approach attempted to recanalize occluded R SFA stents with antegrade approach using 4-Fr Quickcross catheter and Glidewire
Recanalization

- Pullback angiogram demonstrated no acute thrombus
- Predilated entire occluded SFA segment with 5 mm balloon
- Deployed 4 overlapping 6 mm x 15 cm Viabahn stent grafts
Recanalization

- A 7 x 4 cm DES (Zilver PTX) extended into distal R CFA
- Entire segment postdilated to 6 mm
Final Angiogram
Immediate Postprocedure Plan

- Left CFA closure:
  - 6-Fr Angioseal Evolution
- Plavix loaded (300 mg)
- Bridged to Coumadin with Lovenox
- Arterial LE Noninvasive eval the following morning
Arterial LE Noninvasive, 11/1
Postprocedure Management

- Plavix 75 mg daily x 3 months
- Hold ASA 81 mg daily until 3 months
- Encouraged to continue exercise
- Will follow-up with Dr. Benenati before leaving for NJ or in 1 month
2 weeks later (11/16)...

- Presents with cold, acutely painful right foot
Following heparinization and overnight thrombolysis

Overlapping DES (6x100, 6x80) deployed distally
Postprocedure Noninvasive, 11/18

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Postprocedure Plan

- Following successful right SFA/Pop A. recanalization:
  - Postprocedure AKI – improved on discharge
  - Prescribed anticoagulation + dual antiplatelet
  - Follow-up as outpatient in 1 month
Follow-up, 12/8
TIME IS BRAIN
INDIGO™ System – Percutaneous Mechanical Thrombectomy

- Mechanical Clot Engagement and Extraction
  - Unique separator allows clot engagement and extraction into the Indigo catheter without losing access

- Maximized extraction lumen for efficient clot removal
INDIGO™ System – Percutaneous Mechanical Thrombectomy

- Simple and effective
  - Easy-to-use single operator design
  - Penumbra MAX Pump delivers almost pure vacuum and allows for hands free aspiration assistance, with no time limits
History

- 57 y/o male former heavy smoker, non-compliant with statin therapy.
  - Presented with 6 months of progressive right calf claudication.
    - First noticed when he was running between airport gates.
Non-invasive imaging
RLE angiogram – Day 1
RLE angiogram – Day 1
SFA recanalization – Day 1
Angiojet with distal protection
Post Angiojet thrombectomy
Distal emboli
Thrombolysis initiation

10 cm UniFuse catheter across distal SFA and popliteal artery

180 cm Katzen wire in proximal PTA
Day 2 – post 24 hours thrombolysis
Day 2 – post 24 hours thrombolysis
Post tibial artery – standing contrast column
Mechanical Embolectomy:
6F x 0.70 Penumbra Neuron with vacuum suction.
RLE angiogram - Post Mechanical Embolectomy with Penumbra
RLE angiogram - Post Mechanical Embolectomy
RLE angiogram - Post Mechanical Embolectomy
Right SFA: 6mm x 80mm Zilver
PTX
Tomorrow: You Don’t Want to Don’t Miss This!!!

DEB

/O graphe /DE

S

Miami Cancer Center Vascular Institute

BPH

Pulmonary embolism

Roboticics

Imaging Integration

Nano delivery

Oncology

CLI

Obesity

Bio-absorbable devices

Radiation safety