The RESCUE Clinical Trial: Status and Initial Results

Alexander S. Yevzlin, MD
Associate Prof. of Medicine
Director of Interventional Nephrology
University of Wisconsin

RESCUE Study Investigators
- National PIs:
  - Alexander Yevzlin, M.D.
  - Abigail Falk, M.D.
  - Ivan Maya, M.D.
- Site PIs
  - Jeffrey Haggard, M.D.
  - Pablo Margota, M.D.
  - Randy Cooper, M.D.
  - Ahmad Kamel, M.D.
  - Jaime Uzan, M.D.
  - Mignon Choe, M.D.
  - Vajer Ali, M.D.
  - Jihad Lichaa, M.D.
  - George Ljubkovic, M.S.
  - Jeffrey Tablin, M.D.
  - Melvin Rossenborti, M.D.
  - Naveen Arroy, M.D.
  - Samuel Keating, M.D.
  - Anthony Saquman, M.D.
  - Anthony Becker, M.D.
  - Christopher Callout, M.D.
  - Daniel Stenger, M.D.
  - Erika Berrier, M.D.
  - Eric Lalonde, M.D.
  - Lee Khoo, M.D.
  - Savvas Hadjikakos, M.D.
  - Angelo Matris, M.D.

RESCUE Study Background
- Use of bare metal stents in the access circuit remains controversial but...
- The number of stents placed in the access circuit has outpaced PTA each year

RESCUE Study Background

RESCUE Study Background
- ePTFE covered stents in the access circuit

RESCUE Study Overview
- Prospective, multi-center, randomized, concurrently controlled
- 23 US Investigational sites
- Randomization 1:1 PTA vs. PTA & FLUENCY®
  - Fistulas & AV Graft Patients
  - Peripheral and Central Veins up to 12 mm diameter
  - ISR ≥ 50%, <10cm, extends <3cm beyond stent
  - Second lesions if treated to 30% ≤ residual stenosis
- Mandatory angiogram at 90 Days
Investigational Device

Fluency® Plus Endovascular Stent Graft (C.R. Bard, Inc.)

- Self-expanding Nitinol /ePTFE encapsulation
- Carbon-lined luminal surface
- Diameters 6 mm to 13.5 mm
- Lengths 40 mm to 120 mm

RESCUER Study Endpoints

Safety through 30 days:
- Freedom from adverse events (AEs), localized or systemic, that suggests involvement of AV access circuit

Effectiveness:
- Access Circuit Primary Patency (ACPP)
- Post Intervention Lesion Patency (PLP)
- Index of Patency Function (IPF)
- Post Intervention ACPP and PLP Secondary Patency
- Binary Restenosis at 90 Days

Randomized to Fluency (n=109)

Discontinued Study
PTA = 10 / Fluency = 10
- Lost to Follow-up
- PTA = 0 Fluency = 1
- Withdrawn Consent
- PTA = 1 Fluency = 1
- Withdrawn by Investigator
- PTA = 1 Fluency = 0
- Death
- PTA = 8 Fluency = 8

Patient Disposition

Randomized = 220
- PTA = 111
- Fluency= 109

Treated = 220
- PTA = 111
- Fluency = 109

Completed 6 month follow-up = 200
- PTA =101
- Fluency = 99

Patient Demographics

<table>
<thead>
<tr>
<th>Age</th>
<th>PTA Alone (N=111)</th>
<th>FLUENCY® (N=109)</th>
<th>All Subjects (N=220)</th>
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<tbody>
<tr>
<td></td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
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<tr>
<td>Mean</td>
<td>62.6 (13.5)</td>
<td>60.8 (13.4)</td>
<td>61.7 (13.7)</td>
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<tr>
<td>Median</td>
<td>60.7</td>
<td>59.0</td>
<td>60.4</td>
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<tr>
<td>Min, Max</td>
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<td>34,89</td>
<td>27,93</td>
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<table>
<thead>
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<th>Sex</th>
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<tbody>
<tr>
<td></td>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
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<tr>
<td>Male</td>
<td>57 (51.4)</td>
<td>57 (52.3)</td>
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<td>Female</td>
<td>54 (48.6)</td>
<td>52 (47.7)</td>
<td>106 (48.2)</td>
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<table>
<thead>
<tr>
<th>Ethnicity</th>
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<th>FLUENCY® (N=109)</th>
<th>All Subjects (N=220)</th>
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<tbody>
<tr>
<td>Non-Hispanic or Latino</td>
<td>100 (90.1)</td>
<td>93 (85.3)</td>
<td>193 (87.7)</td>
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<td>Hispanic or Latino</td>
<td>11 (9.9)</td>
<td>16 (14.7)</td>
<td>27 (12.3)</td>
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<table>
<thead>
<tr>
<th>Race</th>
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<th>FLUENCY® (N=109)</th>
<th>All Subjects (N=220)</th>
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</thead>
<tbody>
<tr>
<td>White</td>
<td>35 (31.5)</td>
<td>47 (43.1)</td>
<td>82 (37.3)</td>
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<tr>
<td>Black/African American</td>
<td>70 (63.1)</td>
<td>60 (55.0)</td>
<td>130 (59.1)</td>
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<td>Asian</td>
<td>1 (0.9)</td>
<td>1 (0.9)</td>
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<td>Native Hawaiian or Other Pacific Islander</td>
<td>0 (0.0)</td>
<td>1 (0.9)</td>
<td>1 (0.5)</td>
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<tr>
<td>American Indian or Alaskan Native</td>
<td>2 (1.8)</td>
<td>0 (0.0)</td>
<td>2 (0.9)</td>
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<tr>
<td>Other</td>
<td>108 (97.3)</td>
<td>108 (99.1)</td>
<td>216 (98.2)</td>
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</table>

Pre Existing Medical Conditions

<table>
<thead>
<tr>
<th>Category</th>
<th>PTA Alone (N=111)</th>
<th>FLUENCY® (N=109)</th>
<th>All Subjects (N=220)</th>
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<tbody>
<tr>
<td>n (%)</td>
<td>n (%)</td>
<td>n (%)</td>
<td></td>
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<tr>
<td>Congestive Heart Failure</td>
<td>34 (30.6)</td>
<td>29 (26.6)</td>
<td>63 (28.6)</td>
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<tr>
<td>Coronary Heart Disease</td>
<td>31 (28.6)</td>
<td>46 (42.2)</td>
<td>87 (39.6)</td>
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<td>Diabetes Mellitus</td>
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<td>Hyperlipidemia</td>
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<td>3 (2.8)</td>
<td>5 (2.3)</td>
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<td>Hypertension</td>
<td>105 (94.6)</td>
<td>100 (91.7)</td>
<td>205 (93.2)</td>
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<td>Glomerulonephritis</td>
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<td>6 (2.7)</td>
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<td>Peripheral Vascular Disease</td>
<td>14 (12.6)</td>
<td>12 (11.0)</td>
<td>26 (11.8)</td>
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<tr>
<td>Stroke Syndrome</td>
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<td>3 (2.8)</td>
<td>5 (2.3)</td>
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<tr>
<td>Cerebrovascular Accident</td>
<td>14 (13.5)</td>
<td>24 (22.0)</td>
<td>39 (17.7)</td>
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<tr>
<td>Transient Ischemic Attack</td>
<td>0 (0.0)</td>
<td>4 (3.7)</td>
<td>10 (4.5)</td>
</tr>
<tr>
<td>Other</td>
<td>108 (97.3)</td>
<td>108 (99.1)</td>
<td>216 (98.2)</td>
</tr>
</tbody>
</table>
Clinical Indicators

<table>
<thead>
<tr>
<th></th>
<th>PTA Alone  (N=111)</th>
<th>FLUENCY® (N=109)</th>
<th>All Subjects (N=220)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abnormal Physical Exam</td>
<td>54 (48.6)</td>
<td>53 (48.6)</td>
<td>107 (48.6)</td>
</tr>
<tr>
<td>Decreased Access Flow</td>
<td>15 (13.5)</td>
<td>21 (19.3)</td>
<td>36 (16.4)</td>
</tr>
<tr>
<td>Pulling Thrombus</td>
<td>3 (2.7)</td>
<td>4 (3.7)</td>
<td>7 (3.2)</td>
</tr>
<tr>
<td>Increased Recirculation</td>
<td>1 (0.9)</td>
<td>1 (0.9)</td>
<td>2 (0.9)</td>
</tr>
<tr>
<td>Abnormal Pressure Monitoring</td>
<td>16 (14.4)</td>
<td>10 (9.2)</td>
<td>26 (11.8)</td>
</tr>
<tr>
<td>Difficulties w/ Dialysis Needle Puncture</td>
<td>9 (8.1)</td>
<td>5 (4.6)</td>
<td>14 (6.4)</td>
</tr>
<tr>
<td>Prolonged Bleeding</td>
<td>22 (19.8)</td>
<td>17 (15.6)</td>
<td>39 (17.7)</td>
</tr>
<tr>
<td>Inadequate Dialysis Clearance</td>
<td>4 (3.7)</td>
<td>4 (3.7)</td>
<td>8 (3.6)</td>
</tr>
<tr>
<td>Other</td>
<td>60 (54.1)</td>
<td>57 (52.3)</td>
<td>117 (53.2)</td>
</tr>
</tbody>
</table>

220 Patients (ITT)

AV Grafts: 45.5%
AV Fistulae: 54.5%
Arteriovenous Access Type

Stenoses Characteristics

220 Patients (ITT)

Stenosis Location
- Central: 12.2%
- Peripheral: 87.8%

Presence of Second Stenosis
- Second Stenosis: 54%
- No Second Stenosis: 46%

Post Procedure Success

Absence from Residual Stenosis > 30% at Target Lesion post Index Procedure

- Fluency: 70%
- PTA: 24%

Safety through 30 days (ITT)

Freedom From Any Safety Event through 30 days (ITT)

- Fluency: 97%
- PTA: 97%

PLP at 6 Months (ITT)

Percentage of Post Intervention Lesion Patency at 6 Months (95% CI)

- Fluency: 65%
- PTA: 10%

*The 95% Confidence Interval uses a normal approximation with Greenwood’s estimate of variance
**Summary and Conclusion**

- Compared to PTA treatment, the Fluency® Plus Endovascular Stent Graft demonstrated:
  - Non-inferiority for Safety at 30 days
  - Superiority for Post Intervention Lesion Patency at 6 months for the study population and both strata, AV Grafts and AV Fistulae
- Use of the stent graft reduced the risk of PLP failure by 82%
- There was no significant difference in PLP through 6 months between AV Graft and Fistula groups ($p = 0.151$); however, there was statistical significance between central v. peripheral vein locations ($p = 0.023$).