Basic Data Underlying Clinical Decision Making in Endovascular Therapy

Endovascular Abdominal Aortic Aneurysm Repair: Part I

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Endovascular repair of infrarenal abdominal aortic aneurysms has become a well-established and safe treatment modality. Since its development in 1991 by Juan Parodi, an increasing number of procedures have been performed worldwide. The advantages of an endovascular approach include decreased blood loss, length of hospitalization, and early morbidity and mortality. Endovascular therapy is particularly well-suited for the elderly, higher-risk patient and for those with prior aortic operations. This review summarizes the world’s literature to date regarding endovascular aortic aneurysm repair in table form and should serve as a practical and prompt literature search tool.

INTRODUCTION

Endovascular repair has become a widely accepted treatment for abdominal aortic aneurysms. The advantages of an endovascular approach include decreased blood loss, length of hospitalization, and early morbidity and mortality. Endovascular therapy is ideally suited for the elderly, higher-risk patient and for those with prior aortic operations. Properly selected patients have a relatively low incidence of secondary problems including migration, endoleak, and sac expansion. Aneurysm rupture is uncommon in patients who adhere to follow-up surveillance.

Since the first report on the use of endovascular stent grafts by Juan Parodi and associates in 1991, substantial advances have been made in every aspect of endovascular technology. Innovations in catheters, wires, balloons, stent grafts, smaller profile and rapid exchange systems, and intravascular ultrasound have been incorporated into the endovascular practice by most vascular surgeons. In the United States, there are currently five stent grafts approved by the Food and Drug Administration for treatment of abdominal aortic aneurysms: Zenith® (Cook, Bloomington, IN), Excluder® (Gore, Flagstaff, AZ), AneuRx® and Talent® (Medtronic, Sunnyvale, CA), and Powerlink® (Endologix, Irvine, CA). Anatomic limitations are similar for all devices, including the minimum proximal neck length of 1.5 cm for abdominal and 2.0 cm for thoracic aneurysms. The Talent abdominal aortic stent graft is approved for use in patients with a shorter neck length of 1 cm.

In this summary, we have reviewed the world’s literature regarding endovascular aneurysm repair (EVAR). For the sake of clarity, we have elected to separate our review into two sections: (1) elective

Table 1. Epidemiologic Data (EVAR trials)

<table>
<thead>
<tr>
<th>Overall incidence of AAA</th>
<th>12-15/100,000 persons-year</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Age</th>
<th>Mean</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>73.7 yr</td>
<td>(47-98)</td>
<td></td>
</tr>
</tbody>
</table>

Gender

Male: Female ratio

Average: 6:1

(49031 males/8556 females)

References

4

5-79

5-57, 61-79
### Table II. Risk Factors

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>Incidence</th>
<th>Range</th>
<th>Average (n)</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic Renal Failure</td>
<td>3-38%</td>
<td>6% (1023/16926)</td>
<td>6%</td>
<td>5, 8, 10, 12-14, 19, 25, 28-32, 34, 35, 41, 45, 46, 50, 57, 60-64, 79, 80</td>
</tr>
<tr>
<td>Carotid Artery Disease</td>
<td>5-65%</td>
<td>8% (742/8845)</td>
<td></td>
<td>5, 12-14, 24, 28, 45, 46, 59, 61</td>
</tr>
<tr>
<td>Obesity</td>
<td>2-27%</td>
<td>8% (2843/37659)</td>
<td></td>
<td>5, 17, 22, 46, 81</td>
</tr>
<tr>
<td>Family History</td>
<td>2-13%</td>
<td>10% (110-1143)</td>
<td>6, 22, 26, 37, 81</td>
<td>6</td>
</tr>
<tr>
<td>Valvular Disease</td>
<td>11-38%</td>
<td>12% (3828/30685)</td>
<td>22, 32, 67, 81</td>
<td>5, 6, 12-16, 18, 19, 22, 24-26, 28-32, 35, 41, 43, 45-47, 50, 57, 59, 61, 62, 64, 67, 69, 70, 79</td>
</tr>
<tr>
<td>Diabetes Mellitus</td>
<td>4-55%</td>
<td>15% (7200/47880)</td>
<td>6, 12-14, 17, 19, 22, 28, 45, 46, 59, 61</td>
<td></td>
</tr>
<tr>
<td>Congestive Heart Failure</td>
<td>4-52%</td>
<td>15% (5366/34639)</td>
<td>10, 22, 26, 31, 32, 37, 58, 60, 67</td>
<td></td>
</tr>
<tr>
<td>Cerebrovascular Disease</td>
<td>2-26%</td>
<td>16% (4997/31705)</td>
<td>16, 18, 19, 22, 29, 31, 47, 57, 60, 67, 79, 80</td>
<td></td>
</tr>
<tr>
<td>PAD*</td>
<td>10-39%</td>
<td>21% (6764/3177)</td>
<td>8, 22, 26, 29, 34, 35, 57, 63, 67, 72, 80, 81</td>
<td></td>
</tr>
<tr>
<td>Chronic Pulmonary Disease</td>
<td>8-70%</td>
<td>29% (13747/47523)</td>
<td>5, 6, 10, 12-14, 16-19, 22, 26, 28, 29, 31, 34, 35, 37, 41, 45-47, 50, 53, 57, 59-61, 63, 64, 69, 70, 79</td>
<td></td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>14-56%</td>
<td>34% (3784/11080)</td>
<td>5, 13, 14, 16, 19, 28, 29, 31, 35, 45, 46, 61, 62, 64, 79, 80</td>
<td></td>
</tr>
<tr>
<td>Current Smoker</td>
<td>11-87%</td>
<td>38% (4844/12835)</td>
<td>5, 6, 8, 13-16, 22, 24, 28, 31, 32, 35, 43, 45-47, 59, 61, 62, 69, 70, 80</td>
<td></td>
</tr>
<tr>
<td>Ischemic Heart Disease</td>
<td>13-83%</td>
<td>45% (8846/19411)</td>
<td>5, 6, 8, 10, 12-19, 25-32, 34, 35, 37, 41, 45-47, 50, 53, 57-64, 70, 79, 80</td>
<td></td>
</tr>
<tr>
<td>Previous Smoker</td>
<td>23-82%</td>
<td>64% (1596/2506)</td>
<td>6, 8, 12, 13, 15, 22, 24, 37, 47, 81</td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>27-85%</td>
<td>60% (27469/45482)</td>
<td>5, 6, 8, 12-14, 16, 18, 19, 22, 25, 26, 28-32, 35, 37, 41, 45-47, 58, 60-63, 67, 70, 79, 81</td>
<td></td>
</tr>
</tbody>
</table>

*PAD = Peripheral Arterial Disease

### Table III. Aneurysm Features

<table>
<thead>
<tr>
<th>Risk Factor</th>
<th>Incidence</th>
<th>Range</th>
<th>Average</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neck diameter (mm)</td>
<td></td>
<td>17.9-25.3</td>
<td>23.7</td>
<td>12, 22, 23, 26, 27, 42, 53, 55, 57, 79, 82-86</td>
</tr>
<tr>
<td>Neck length (mm)</td>
<td></td>
<td>8-70</td>
<td>24.6</td>
<td>6, 26, 68, 79, 82, 86-89</td>
</tr>
<tr>
<td>Neck Angle (degrees)</td>
<td></td>
<td>5-90</td>
<td>31</td>
<td>6, 68, 79, 82, 86, 90</td>
</tr>
<tr>
<td>Largest Diameter (mm)*</td>
<td></td>
<td>50-110</td>
<td>58</td>
<td>5, 6, 8, 10, 12, 15, 18, 19, 21, 22, 24-29, 32, 33, 35-39, 42, 45-48, 51, 53, 55, 57, 59, 60, 63, 69, 74, 77, 79, 84, 91</td>
</tr>
<tr>
<td>Length Renal-Iliac artery (mm)</td>
<td></td>
<td>119-188</td>
<td>164</td>
<td>53, 82, 90</td>
</tr>
</tbody>
</table>

*Studies including AAA ≥ 5 cm

### Table IV. Type of Anesthesia and Risk Stratification

<table>
<thead>
<tr>
<th>Type of Anesthesia</th>
<th>Incidence</th>
<th>Range</th>
<th>Average (n)</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>General</td>
<td>4-100%</td>
<td>61% (6569/10744)</td>
<td>5, 11-14, 17, 19, 24, 27, 32, 46, 55, 58, 61, 81, 88, 92</td>
<td></td>
</tr>
<tr>
<td>Regional</td>
<td>2-95%</td>
<td>34% (3491/10319)</td>
<td>5, 11-14, 17, 19, 27, 35, 46, 58, 61, 88, 92</td>
<td></td>
</tr>
<tr>
<td>Local</td>
<td>1-71%</td>
<td>8% (705/8684)</td>
<td>5, 11-13, 19, 28, 46, 61, 92</td>
<td></td>
</tr>
<tr>
<td>Conversion LA to GA*</td>
<td>0-15%</td>
<td>3% (15/561)</td>
<td>22, 28, 45, 46, 57, 61, 75, 91</td>
<td></td>
</tr>
<tr>
<td>ASA I</td>
<td>0-42%</td>
<td>10% (342/3453)</td>
<td>13, 22, 28, 29, 42, 45, 46, 57, 61, 70, 75, 81, 91</td>
<td></td>
</tr>
<tr>
<td>ASA II</td>
<td>5-70%</td>
<td>34% (1544/4557)</td>
<td>13, 22, 27-29, 39, 42, 45, 46, 57, 61, 70, 75, 81, 91, 96</td>
<td></td>
</tr>
<tr>
<td>ASA III</td>
<td>8-91%</td>
<td>52% (2721/5245)</td>
<td>12, 13, 19, 22, 27-29, 42, 57, 70, 75, 81, 91, 96</td>
<td></td>
</tr>
<tr>
<td>ASA IV</td>
<td>4-57%</td>
<td>17% (906/5290)</td>
<td>5, 28, 43</td>
<td></td>
</tr>
</tbody>
</table>

*LA/GA = Local Anesthesia/General Anesthesia;^1 Society for Vascular Surgery Score
## Table V. Procedure Data

<table>
<thead>
<tr>
<th>Variables</th>
<th>Range</th>
<th>Average (N)</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deployment Success, %</td>
<td>85-100</td>
<td>95</td>
<td>7, 8, 11, 12, 15, 21, 24, 33, 35, 38, 42, 46, 48, 51, 52, 57, 59, 60, 65, 69, 75, 80, 90, 97, 98</td>
</tr>
<tr>
<td>Duration of Procedure, min</td>
<td>35-846</td>
<td>168</td>
<td>5, 11, 12, 15, 17-19, 36, 38, 43, 46, 49, 55, 58, 59, 76, 78, 80, 92, 99</td>
</tr>
<tr>
<td>Blood Loss, ml</td>
<td>50-1700</td>
<td>354</td>
<td>11, 12, 16, 18, 19, 24, 26, 36, 37, 43, 58, 59, 76, 80, 92</td>
</tr>
<tr>
<td>Media Contrast, ml</td>
<td>88-195</td>
<td>145</td>
<td>15, 30, 41, 53, 55, 81, 100, 101</td>
</tr>
<tr>
<td>Any iliac intervention %*</td>
<td>2-17</td>
<td>8 (176/2134)</td>
<td>10, 13, 24, 26, 29, 35, 38, 97, 99</td>
</tr>
<tr>
<td>Additional Procedure, %</td>
<td>2-31</td>
<td>23 (2118/9045)</td>
<td>5, 8, 10, 11, 21, 24, 28</td>
</tr>
<tr>
<td>Conversion to open repair %</td>
<td>0-5.5</td>
<td>2 (859/48637)</td>
<td>5, 7, 10, 11, 13, 16, 17, 19, 21, 24-26, 29, 33, 35, 38-40, 42, 47, 48, 51, 57, 59, 66, 73, 77, 98, 102-104</td>
</tr>
<tr>
<td>Transfusion, [U]</td>
<td>0-4.8</td>
<td>0.6</td>
<td>10, 11, 15, 23, 29, 31, 32, 46, 49, 59, 60, 80, 86, 92</td>
</tr>
<tr>
<td>ICU length of Stay (days)</td>
<td>0-48</td>
<td>2.3</td>
<td>5, 6, 10-12, 15, 16, 19, 20, 26, 29, 31, 34, 37, 37-41, 44, 46, 49, 55, 59, 63, 67, 70, 72, 76, 80, 86, 92, 105</td>
</tr>
<tr>
<td>Hospital length of Stay (days)</td>
<td>1-43</td>
<td>5</td>
<td>72, 76, 80, 86, 92, 105</td>
</tr>
</tbody>
</table>

*Need for iliac artery angioplasty/stenting or endarterectomy prior to EVAR

## Table VI. Incidence according to model and US-commercially available devices*

<table>
<thead>
<tr>
<th>Pattern</th>
<th>Incidence (N)</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bifurcated</td>
<td>52-98% 86% (11266/13048)</td>
<td>7, 11, 12, 14, 15, 18, 19, 21, 24, 26, 34-36, 46, 57, 66, 75, 81, 82, 91</td>
</tr>
<tr>
<td>Tubular</td>
<td>1-48% 9% (1013/11538)</td>
<td>7, 11, 14, 18, 19, 21, 34-36, 46, 57, 66, 75, 81, 82, 91</td>
</tr>
<tr>
<td>Aortouniiliac + Crossover</td>
<td>0-26% 5% (470/10100)</td>
<td>7, 11, 12, 14, 15, 19, 21, 26, 34-36, 46, 66, 75</td>
</tr>
</tbody>
</table>

### Devices (Company)

<table>
<thead>
<tr>
<th>Devices (Company)</th>
<th>Incidence (N)</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zenith® (Cook Medical, Inc)</td>
<td>6-82% 35% (4316/12483)</td>
<td>11, 13-15, 19, 21, 24, 25, 28, 29, 32, 35, 37, 39, 55, 56, 66, 70, 71, 92, 98, 106</td>
</tr>
<tr>
<td>AneuRx® (Medtronic, Inc)</td>
<td>4-86% 29% (4552/15516)</td>
<td>10, 11, 13-15, 17, 19, 21, 24-26, 32, 35, 37, 39, 55-57, 59, 62, 66, 70-72, 74, 98, 106</td>
</tr>
<tr>
<td>Talent® ((Medtronic, Inc)</td>
<td>0.5-65% 22% (2682/12419)</td>
<td>5, 7, 11, 12, 14, 15, 19, 21, 24, 26, 28, 29, 37, 39, 56, 57, 106</td>
</tr>
<tr>
<td>Excluder® (Gore Medical,Inc)</td>
<td>1-40% 12% (1928/15841)</td>
<td>13-15, 19, 21, 24-26, 28, 29, 32, 35, 37, 39, 55, 56, 62, 66, 70, 71, 74, 92, 98, 106</td>
</tr>
<tr>
<td>Powerlink® (Endologix,Inc)</td>
<td>1-38% 4% (400/10823)</td>
<td>10, 19, 25, 32, 35, 57, 66, 71, 98, 106</td>
</tr>
</tbody>
</table>

*Data from Mixed Graft trials (For the US Pivotal/Multicenter trials refer to Table XVIIA/B)

## Table VII. Early Complications (<30 days)

<table>
<thead>
<tr>
<th>Incidence</th>
<th>Range</th>
<th>Average (No of patients)</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory Impairment</td>
<td>1-12%</td>
<td>9% (2818/32582)</td>
<td>8-10, 12, 17, 28, 36, 44, 64, 67, 72, 78, 98</td>
</tr>
<tr>
<td>Unstable Angina/ MI*</td>
<td>1-5%</td>
<td>7% (2114/31559)</td>
<td>7, 10, 12, 28, 36, 48, 51, 63, 64, 67, 73, 80, 86, 98</td>
</tr>
<tr>
<td>Access hematoma</td>
<td>1-5%</td>
<td>4% (23/560)</td>
<td>11, 34, 51, 57, 75</td>
</tr>
<tr>
<td>Lymphocele/leak</td>
<td>0-5%</td>
<td>3% (32/1054)</td>
<td>10, 12, 48, 51, 64, 75, 80, 107</td>
</tr>
<tr>
<td>Wound Infection</td>
<td>0-11%</td>
<td>3% (119/3744)</td>
<td>8, 10-12, 28, 31, 44, 46, 51, 64, 64, 72, 78, 80, 98</td>
</tr>
<tr>
<td>Graft Limb Thrombosis</td>
<td>0-7%</td>
<td>3% (110/4232)</td>
<td>10-12, 15, 31, 33, 38, 40, 46, 47, 51, 57, 59, 60, 64, 65, 69, 86, 104</td>
</tr>
<tr>
<td>Access-related rupture/dissection</td>
<td>1-4%</td>
<td>2% (13/695)</td>
<td>6, 10, 12, 51, 57, 81</td>
</tr>
<tr>
<td>Pseudoaneurysm</td>
<td>0-1%</td>
<td>1% (6/554)</td>
<td>26, 57, 108</td>
</tr>
<tr>
<td>Ileus</td>
<td>0-1%</td>
<td>1% (4/486)</td>
<td>12, 57, 72</td>
</tr>
<tr>
<td>Stroke</td>
<td>0-1%</td>
<td>0.6% (5/865)</td>
<td>8, 12, 36, 58, 64, 80</td>
</tr>
<tr>
<td>Bowel Ischemia</td>
<td>0-2%</td>
<td>0.4% (36/8806)</td>
<td>8, 36, 42, 57, 59, 86, 109, 110</td>
</tr>
<tr>
<td>Paraplegia</td>
<td>0-1%</td>
<td>0.2% (7/2923)</td>
<td>17, 111</td>
</tr>
<tr>
<td>AAA Rupture</td>
<td>0-0.5%</td>
<td>0.1% (8/10025)</td>
<td>22, 32, 39, 91</td>
</tr>
</tbody>
</table>

*MI = Miocardial Infarction
EVAR for nonruptured abdominal aortic aneurysms (AAAs) and (2) EVAR for ruptured AAAs. This review will attempt to summarize all available data for elective EVAR of nonruptured AAAs in table form. The data for EVAR of ruptured AAAs will be included in a separate summary.

The literature search for this review was performed using the MEDLINE and EMBASE databases.

Table VIII. Late Complications (>30 days)

<table>
<thead>
<tr>
<th>Incidence</th>
<th>Range</th>
<th>Average (No of patients)</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Secondary Procedure</td>
<td>4-82%</td>
<td>13% (1146/8789)</td>
<td>9, 10, 12, 15, 17, 19, 25, 26, 35, 40, 46, 52, 53, 55-57, 59, 60, 68, 78, 81, 84, 105, 112,113</td>
</tr>
<tr>
<td>AAA enlargement*</td>
<td>1-11%</td>
<td>6% (139/2442)</td>
<td>12, 26, 32, 34, 40, 56, 57, 68, 81, 113, 114</td>
</tr>
<tr>
<td>Graft Migration</td>
<td>0-16%</td>
<td>3% (299/8917)</td>
<td>6, 12, 15, 27, 32, 33, 35, 38, 40, 42, 46, 51, 56, 58, 68, 71, 77, 78, 83, 105, 115, 116</td>
</tr>
<tr>
<td>AAA Rupture</td>
<td>0-2%</td>
<td>2% (471/29406)</td>
<td>10, 12, 22, 32, 35, 39, 40, 51, 59, 67, 79, 91, 112</td>
</tr>
<tr>
<td>Graft Infection</td>
<td>0-1%</td>
<td>0.5% (12/2265)</td>
<td>15, 40, 57, 71, 112, 117, 118</td>
</tr>
</tbody>
</table>

*AAA measurement - follow up ≤ 2 years

Table IX. Internal Iliac Artery and Buttock Claudication postEVAR

<table>
<thead>
<tr>
<th>Incidence</th>
<th>Variable</th>
<th>Range</th>
<th>Average (N)</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>4-69%</td>
<td>Intentional IIA Occlusion</td>
<td>11% (1287/11431)</td>
<td>97, 119-138</td>
<td></td>
</tr>
<tr>
<td>2-50%</td>
<td>Buttock Claudication*</td>
<td>18% (233/1287)</td>
<td>97, 119-138</td>
<td></td>
</tr>
</tbody>
</table>

IIA = Internal Iliac Artery

*Postunilateral and/or bilateral IIA occlusion

Table X. Sexual Dysfunction postEVAR and Open Repair

<table>
<thead>
<tr>
<th>Incidence</th>
<th>Variable</th>
<th>Range</th>
<th>Average (N)</th>
<th>Preoperative Sexual Dysfunction</th>
<th>Postoperative Sexual Dysfunction (new onset)</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>108</td>
<td>Mehta et al, 2001</td>
<td>34</td>
<td>-</td>
<td>-</td>
<td>6</td>
<td>4</td>
</tr>
<tr>
<td>18</td>
<td>Mehta et al, 2004</td>
<td>10</td>
<td>-</td>
<td>-</td>
<td>11</td>
<td>20</td>
</tr>
<tr>
<td>77</td>
<td>Prinssen et al, 2004</td>
<td>76</td>
<td>74</td>
<td>66</td>
<td>53</td>
<td>66</td>
</tr>
<tr>
<td>21</td>
<td>Koo et al, 2007</td>
<td>26</td>
<td>27</td>
<td>62*</td>
<td>76</td>
<td>58*</td>
</tr>
<tr>
<td>224</td>
<td>Total</td>
<td>146</td>
<td>42</td>
<td>64</td>
<td>40</td>
<td>33</td>
</tr>
</tbody>
</table>

QoL = Quality of Life; OR = Open Repair

°Data from DREAM trial – 3-months-follow-up

*p< 0.05

Table XI. Renal Failure

<table>
<thead>
<tr>
<th>Incidence</th>
<th>Range</th>
<th>Average (N)</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Renal Failure</td>
<td>0-17%</td>
<td>5% (1811/33687)</td>
<td>7, 8, 10-12, 21, 24, 28, 30, 31, 36, 48, 51, 63, 67, 72, 73, 86</td>
</tr>
<tr>
<td>Need for dialysis</td>
<td>0-3%</td>
<td>0.4% (130/30665)</td>
<td>7, 8, 11, 12, 30, 51, 67, 86, 98</td>
</tr>
</tbody>
</table>
### Table XII. Early Endoleak (<30 days)

<table>
<thead>
<tr>
<th>Classification</th>
<th>Incidence</th>
<th>Average (n)</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type I</td>
<td>0-26%</td>
<td>4% (473/11411)</td>
<td>5, 8, 10, 12, 14, 17, 19, 21, 26, 34, 38, 46, 48, 62, 80, 102, 115, 139</td>
</tr>
<tr>
<td>Type Ia</td>
<td>1-5%</td>
<td>3% (264/8688)</td>
<td>5, 21, 65, 140, 141</td>
</tr>
<tr>
<td>Type II</td>
<td>1-26%</td>
<td>9% (1032/11304)</td>
<td>5, 8, 10, 14, 17, 19, 21, 26, 34, 38, 46, 48, 62, 65, 80, 102, 115, 139</td>
</tr>
<tr>
<td>Type III</td>
<td>0-5%</td>
<td>2% (165/9360)</td>
<td>5, 10, 17, 21, 26, 38, 46, 48, 65, 80, 102, 139</td>
</tr>
<tr>
<td>Overall Endoleak</td>
<td>0-23%</td>
<td>15% (1635/11234)</td>
<td>5, 7, 14, 17, 19, 21, 26, 32-34, 38, 46, 57, 62, 73, 102, 139</td>
</tr>
</tbody>
</table>

### Table XIII. Late Endoleak (>30 days)

<table>
<thead>
<tr>
<th>Classification</th>
<th>Incidence</th>
<th>Average (n)</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type I</td>
<td>0-25%</td>
<td>6% (248/4477)</td>
<td>12, 14, 33, 38, 51, 56, 57, 62, 68, 73, 74, 76, 84, 88, 102, 115, 142</td>
</tr>
<tr>
<td>Type Ia</td>
<td>0-8%</td>
<td>4% (43/1212)</td>
<td>19, 46, 73, 143</td>
</tr>
<tr>
<td>Type II</td>
<td>1-81%</td>
<td>12% (377/3205)</td>
<td>12, 14, 33, 38, 51, 57, 62, 68, 73, 74, 76, 84, 88, 102, 115, 142</td>
</tr>
<tr>
<td>Type III</td>
<td>0-7%</td>
<td>1% (22/1767)</td>
<td>12, 14, 33, 38, 57, 69, 73, 74, 102</td>
</tr>
<tr>
<td>Overall Endoleak</td>
<td>4-38%</td>
<td>17% (795/4712)</td>
<td>6, 7, 10, 12, 14, 22, 32, 35, 40, 51, 53, 57, 58, 62, 73, 74, 78, 88, 102, 142</td>
</tr>
</tbody>
</table>

### Table XIV. Early Mortality Causes (<30 days)

<table>
<thead>
<tr>
<th>Causes</th>
<th>Incidence</th>
<th>Average (n)</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedure-related Mortality</td>
<td>1-7%</td>
<td>2% (71/4059)</td>
<td>15, 24, 35, 39, 63, 65, 86</td>
</tr>
<tr>
<td>Cardiac</td>
<td>1-4%</td>
<td>1% (54/7833)</td>
<td>15, 26, 38, 42, 57, 73, 145, 146</td>
</tr>
<tr>
<td>Multiorgan Failure</td>
<td>0-3%</td>
<td>0.4% (33/7730)</td>
<td>17, 26, 35, 36, 42, 57, 147</td>
</tr>
<tr>
<td>Pulmonary</td>
<td>0-1%</td>
<td>0.3% (19/6232)</td>
<td>26, 146, 147</td>
</tr>
<tr>
<td>Rupture</td>
<td>0-2%</td>
<td>0.1% (11/11908)</td>
<td>5, 15, 24, 25, 38, 48, 144</td>
</tr>
</tbody>
</table>

### Table XV. Late Mortality Causes (>30 days)

<table>
<thead>
<tr>
<th>Causes</th>
<th>Incidence</th>
<th>Average (n)</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiac</td>
<td>1-54%</td>
<td>5% (150/2828)</td>
<td>11, 15, 22, 24, 28, 40, 42, 51, 57, 58, 70, 117, 148</td>
</tr>
<tr>
<td>Pulmonary</td>
<td>0-9%</td>
<td>2% (31/1765)</td>
<td>11, 15, 24, 40, 42, 46, 51, 70, 105</td>
</tr>
<tr>
<td>Procedure related-death</td>
<td>0-6%</td>
<td>2% (119/7632)</td>
<td>11, 13, 19, 21, 22, 24, 25, 32, 34, 40, 42, 46, 48, 51, 56, 57, 59, 60, 71, 117</td>
</tr>
<tr>
<td>Multiorgan Failure</td>
<td>0-2%</td>
<td>1% (7/883)</td>
<td>11, 15, 24, 40, 42, 51, 57, 58</td>
</tr>
<tr>
<td>Stroke</td>
<td>0-4%</td>
<td>1% (15/1084)</td>
<td>13, 15, 22, 25, 42, 56, 57, 70, 71, 112, 117</td>
</tr>
<tr>
<td>AAA Rupture</td>
<td>0-2%</td>
<td>1% (53/5445)</td>
<td>6, 11, 14, 20-22, 24, 29, 31, 33-35, 37, 38, 42, 45, 46, 53, 57, 58, 75, 76, 79, 98, 102</td>
</tr>
<tr>
<td>Overall Mortality</td>
<td>0-50%</td>
<td>9% (787/8609)</td>
<td>57, 58, 75, 76, 79, 98, 102</td>
</tr>
</tbody>
</table>
### Table XVI. Mortality and Survival Analysis Comparison between EVAR and Open Repair — EBM* Level I and II Trials

<table>
<thead>
<tr>
<th>Trials</th>
<th>Level of EBM</th>
<th>n</th>
<th>Operative Mortality</th>
<th>1-yr Survival</th>
<th>5-yr Survival</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>EVAR</td>
<td>OR</td>
<td>EVAR (%)</td>
<td>OR (%)</td>
</tr>
<tr>
<td>EVAR-1</td>
<td>I</td>
<td>610</td>
<td>596</td>
<td>10 (1.6)</td>
<td>25 (4.2)</td>
</tr>
<tr>
<td>DREAM I</td>
<td>I</td>
<td>171</td>
<td>174</td>
<td>2 (1.2)</td>
<td>8 (4.6)</td>
</tr>
<tr>
<td>Greenberg et al, 2004</td>
<td>II-1</td>
<td>152</td>
<td>80</td>
<td>1 (0.5)</td>
<td>2 (2.5)</td>
</tr>
<tr>
<td>Zarins et al, 1999</td>
<td>II-1</td>
<td>416</td>
<td>66</td>
<td>5 (3)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Peterson et al, 2007</td>
<td>II-1</td>
<td>235</td>
<td>99</td>
<td>2 (1)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Criado et al, 2001</td>
<td>II-1</td>
<td>240</td>
<td>126</td>
<td>1 (0.8)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Moore et al, 2003</td>
<td>II-1</td>
<td>573</td>
<td>111</td>
<td>1.7 (10)</td>
<td>2.7 (3)</td>
</tr>
<tr>
<td>Wang et al, 2006</td>
<td>II-1</td>
<td>192</td>
<td>66</td>
<td>2 (1)</td>
<td>4 (6)</td>
</tr>
<tr>
<td>Hynes et al, 2007</td>
<td>II-1</td>
<td>66</td>
<td>52</td>
<td>2 (3)</td>
<td>3 (5.8)</td>
</tr>
<tr>
<td>Schermerhorn et al, 2008†‡</td>
<td>II-3</td>
<td>29542</td>
<td>32056</td>
<td>354 (1.2)</td>
<td>1539 (4.8)</td>
</tr>
<tr>
<td>Cao P et al, 2004</td>
<td>II-3</td>
<td>534</td>
<td>585</td>
<td>5 (0.9)</td>
<td>24 (4.1)</td>
</tr>
<tr>
<td>Bush et al, 2006</td>
<td>II-3</td>
<td>717</td>
<td>1187</td>
<td>22 (3.1)</td>
<td>66 (5.6)</td>
</tr>
<tr>
<td>Wanhainem et al, 2008</td>
<td>II-3</td>
<td>1064</td>
<td>9627</td>
<td>56 (5.3)</td>
<td>347 (3.6)</td>
</tr>
</tbody>
</table>

Table Refs: 15, 19, 31, 50, 60, 61, 67, 92, 149-157

*EBM = Evidence-based Medicine
†DREAM trial - 2 yr data available
‡4 yr data
§Greenberg et al, 2008
∥Zarin et al, 2003
US-Medicare data
Veteran’s Affair (VA) National Surgical Quality Improvement Program (NSQIP) data
### Table XVII.A. Device-related outcomes (the US Pivotal/Multicenter Trials)

<table>
<thead>
<tr>
<th>Outcome</th>
<th>AneuRx*</th>
<th>Excluder†</th>
<th>Zenith‡</th>
<th>Talent§</th>
<th>Powerlink [1]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deployment Success Rate</td>
<td>97%</td>
<td>100%</td>
<td>99.6%</td>
<td>98.7%</td>
<td>97.9</td>
</tr>
<tr>
<td>Conversion to OR*</td>
<td>4.5% (53/1193)</td>
<td>4.3% (10/235)</td>
<td>1.3% (8/625)</td>
<td>2.5% (6/240)</td>
<td>6.8% (13/192)</td>
</tr>
<tr>
<td>AAA rupture</td>
<td>1.3% (15/1193)</td>
<td>0 (0/235)</td>
<td>0.1% (1/632)</td>
<td>0 (0/237)</td>
<td>0 (0/190)</td>
</tr>
<tr>
<td>AAA-related death</td>
<td>2.5% (30/1193)</td>
<td>2.5% (6/235)</td>
<td>2.9% (18/615)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Mortality</td>
<td>21% (250/1193)</td>
<td>-</td>
<td>25% (125/508)</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>AAA rupture</td>
<td>1.3% (19/137)</td>
<td>3% (2/68)</td>
<td>6% (36/619)</td>
<td>10% (16/159)</td>
<td>14.3% (4/35)</td>
</tr>
<tr>
<td>AAA Enlargement</td>
<td>11.5% (15/130)</td>
<td>38% (30/79)</td>
<td>6% (31/489)</td>
<td>1.2% (2/159)</td>
<td>10.3% (3/29)</td>
</tr>
<tr>
<td>Sac Shrinkage</td>
<td>36%** (138/383)</td>
<td>21% (16/76)</td>
<td>73%†† (128/175)</td>
<td>59%# (192/323)</td>
<td>82.8% (53/64)</td>
</tr>
<tr>
<td>Graft Migration</td>
<td>9.5% (13/137)</td>
<td>0 (0/235)</td>
<td>2.6% (19/736)</td>
<td>1.9% (3/159)</td>
<td>1.6% (3/190)</td>
</tr>
<tr>
<td>Need for Second Intervention</td>
<td>8% (94/1192)</td>
<td>24% (57/235)</td>
<td>19% (64/555)</td>
<td>-</td>
<td>18% (34/192)</td>
</tr>
<tr>
<td>Proximal. Extension</td>
<td>22% (202/1119)</td>
<td>33% (77/235)</td>
<td>-</td>
<td>-</td>
<td>42% (79/188)</td>
</tr>
<tr>
<td>Fracture Rate</td>
<td>0.16% (18/1119)</td>
<td>0 (0/74)</td>
<td>0 (0/376)</td>
<td>4.6% (11/237)</td>
<td>0 (0/190)</td>
</tr>
<tr>
<td>Survival Rate</td>
<td>62.4%</td>
<td>72%</td>
<td>61%*</td>
<td>-</td>
<td>69.6%</td>
</tr>
<tr>
<td>Freedom from AAA Rupture</td>
<td>98.4%</td>
<td>-</td>
<td>100%</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Freedom from conversion</td>
<td>90.4%</td>
<td>-</td>
<td>98.2%</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Freedom from AAA-related death</td>
<td>96.9%</td>
<td>97%</td>
<td>97.8%</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

*6 yr data \cite{156}  
†5 yr data \cite{149}  
‡5 yr data \cite{157}  
§1 yr data \cite{153, 154}  
‖6 yr data \cite{150, 161}  
||2 yr data \cite{158}  
\asterisk{1} 1 yr data \cite{159}  
\asterisk{2} 2 yr data \cite{160}  
*High-risk patients
Table XVII.B. Device-related outcomes (the US Pivotal/Multicenter Trials)*

<table>
<thead>
<tr>
<th></th>
<th>Guidant/EVT †</th>
<th>Ancure †</th>
<th>Lifepath †</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deployment Success Rate, %</td>
<td>90.3</td>
<td>95.1</td>
<td>98.7</td>
</tr>
<tr>
<td>Conversion to OR</td>
<td>9.7% (26/268)</td>
<td>4.9% (15/305)</td>
<td>2.2% (5/227)</td>
</tr>
<tr>
<td>AAA rupture</td>
<td>0 (319/319)</td>
<td>0 (111/111)</td>
<td>0 (0/227)</td>
</tr>
<tr>
<td>AAA-related death</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Mortality</td>
<td>7% (19/268)</td>
<td>3% (9/305)</td>
<td>6.6% (15/227)</td>
</tr>
<tr>
<td>Overall Endoleak</td>
<td>-</td>
<td>-</td>
<td>6.8% (15/227)</td>
</tr>
<tr>
<td>Type 1 Endoleak</td>
<td>5% (12/242)</td>
<td>6.3% (18/290)</td>
<td>2.9% (7/224)</td>
</tr>
<tr>
<td>AAA Enlargement</td>
<td>2.4% (1/42)</td>
<td>2.4% (1/42)</td>
<td>3% (7/227)</td>
</tr>
<tr>
<td>Sac Shrinkage</td>
<td>78% (33/42)</td>
<td>78% (33/42)</td>
<td>58% (140/242)</td>
</tr>
<tr>
<td>Graft Migration</td>
<td>0.6% (2/319)</td>
<td>0.6% (2/319)</td>
<td>2.2% (5/227)</td>
</tr>
<tr>
<td>Need for Second Intervention</td>
<td>9.1% (22/242)</td>
<td>10.3% (30/290)</td>
<td>7.5% (17/224)</td>
</tr>
<tr>
<td>Proximal. Extension</td>
<td>-</td>
<td>-</td>
<td>17.6% (40/227)</td>
</tr>
<tr>
<td>Fracture Rate</td>
<td>-</td>
<td>-</td>
<td>21.9% (43/196)</td>
</tr>
<tr>
<td>Survival Rate</td>
<td>68.1</td>
<td>77.2</td>
<td>-</td>
</tr>
<tr>
<td>Freedom from AAA Rupture</td>
<td>100%</td>
<td>100%</td>
<td>-</td>
</tr>
<tr>
<td>Freedom from conversion</td>
<td>99.4%</td>
<td>99.4%</td>
<td>-</td>
</tr>
<tr>
<td>Freedom from AAA-related death</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

*Stent-grafts not commercially available in the US
†Combined Analysis EVT/Ancure 151, 152
‡2-year data 162
§5-year follow-up data from Guidant/EVT and Ancure groups 152

Table XVIII. AAA Size-related Outcomes data

<table>
<thead>
<tr>
<th>SMALL (&lt;5 cm)</th>
<th>MEDIUM/LARGE (≥ 5 cm)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Range</td>
</tr>
<tr>
<td>Conversion to open repair</td>
<td>1-3%</td>
</tr>
<tr>
<td>Second Procedure</td>
<td>10-22%</td>
</tr>
<tr>
<td>Type 1 Endoleak</td>
<td>1-4%</td>
</tr>
<tr>
<td>Early mortality</td>
<td>1-2%</td>
</tr>
<tr>
<td>AAA Enlargement</td>
<td>9-10%</td>
</tr>
<tr>
<td>Endograft Migration</td>
<td>4.4%</td>
</tr>
<tr>
<td>AAA Rupture</td>
<td>0-2%</td>
</tr>
</tbody>
</table>

Table XIX. Costs Analysis

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>Preoperative workup</th>
<th>Hospital Charges</th>
<th>Postoperative costs</th>
<th>Total Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>EVAR</td>
<td>OR</td>
<td>EVAR</td>
<td>OR</td>
<td>EVAR</td>
</tr>
<tr>
<td>Values in USS</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Holzenbein et al, 1997</td>
<td>22</td>
<td>22</td>
<td>-</td>
<td>-</td>
<td>-</td>
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<tr>
<td>Patel et al, 1999</td>
<td>-</td>
<td>-</td>
<td>3228</td>
<td>1324</td>
<td>7764</td>
</tr>
<tr>
<td>Seiwert et al, 1999</td>
<td>16</td>
<td>16</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Sternbergh III et al, 2000</td>
<td>131</td>
<td>49</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Bosch et al, 2001</td>
<td>181</td>
<td>273</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Berman et al, 2002</td>
<td>9</td>
<td>11</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Dryjski et al, 2003</td>
<td>73</td>
<td>57</td>
<td>-</td>
<td>-</td>
<td>-</td>
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<tr>
<td>Rosenberg et al, 2005</td>
<td>34</td>
<td>54</td>
<td>-</td>
<td>-</td>
<td>15049</td>
</tr>
<tr>
<td>Hayter et al, 2005</td>
<td>55</td>
<td>140</td>
<td>733</td>
<td>663</td>
<td>12297</td>
</tr>
<tr>
<td>Fotis et al, 2008</td>
<td>37</td>
<td>21</td>
<td>-</td>
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</table>

(Continued)
Table XIX. Continued

<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>Preoperative workup</th>
<th>Hospital Charges</th>
<th>Postoperative costs</th>
<th>Total Costs</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>EVAR</td>
<td>OR</td>
<td>EVAR</td>
<td>OR</td>
<td>EVAR</td>
</tr>
<tr>
<td>Total (Averages)</td>
<td>524</td>
<td>589</td>
<td>1980</td>
<td>993</td>
<td>11703</td>
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<tr>
<td>Values in Euros (€)</td>
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<td></td>
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</tr>
<tr>
<td>Hynes et al, 2007</td>
<td>66</td>
<td>52</td>
<td>415</td>
<td>415</td>
<td>17108</td>
</tr>
<tr>
<td>Mani et al, 2008</td>
<td>51</td>
<td>58</td>
<td>1494</td>
<td>415</td>
<td>20484</td>
</tr>
<tr>
<td>Total (Averages)</td>
<td>117</td>
<td>110</td>
<td>954</td>
<td>538</td>
<td>18796</td>
</tr>
</tbody>
</table>

Ref. 29, 47, 49, 60, 166-174; OR = Open Repair
*Costs calculated based on a hypothetical cohort of patients
†Follow-up values considering only noninvasive exams

focusing on keywords such as “abdominal aortic aneurysm,” “EVAR,” “endovascular,” “endograft,” and “stent graft.” This yielded an abundance of matches consisting of a few thousand papers that have been published over the past 17 years. We refined our search based on number of patients (>30 patients), rationale and design of the study, and type of study (clinical trials, mega-trials, pivotal studies) to include the most practical and current issues related to EVAR.

Data extracted from selected papers were allocated as they appear in crude values or percentages. Specific keywords were used to enrich tables related to endoleak and specific complications like bowel ischemia, buttck claudication, and sexual dysfunction.

We allocated information in tables regarding epidemiology (Table I), risk factors (Table II), aneurysm features (Table III), anesthesia and risk stratification (Table IV), procedure data (Table V), device and graft data (Table VI), and early and late morbidity and mortality results of EVAR including endoleak analysis, sexual dysfunction, buttock claudication, and renal failure (Tables VII–XV). In table XVI, we summarized the mortality and survival results from the available level I and II evidence based on multicenter trials which compared EVAR to open repair (OR). To further compare data for each specific endograft that has been tested and commercially available in the United States, we summarized the device-specific outcomes from the respective U.S. pivotal and multicenter trials with long-term results out to 5 years and compared the results for each endovascular device in Tables XVIIA and XvIIIB.

Controversy still exists over the appropriate aneurysm size threshold for repair of AAA. Currently, the prevailing dogma is to repair AAAs ≥5.5 cm based on population-based study trials.1-3 In addition to indications, costs of EVAR have been scrutinized and compared with those of OR in order to assess the most efficacious and cost-efficient procedure in both the short and long terms. These data are summarized in Tables XVIII and XIX.

The purpose of this report is to not to analyze all data but to provide readers with a synopsis of the most current and important data regarding the key issues in EVAR. We hope that readers find it to be informative, insightful, and helpful to their practice.

REFERENCE


