Latest results of Endurant registries

The ENGAGE Registry

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Erasmus University Medical Center

On behalf of Engage Investigators
Disclosures:

- Consultant for Medtronic
Global results of EVAR

• Well documented in the literature
  – DREAM
  – EVAR
  – OVER
  – ACE

Can these results be extrapolated to the general population?
Global results of EVAR

- Well documented in the literature
  - Small studies
  - Centers of excellence

Can these results be extrapolated to the general population?
Global results of EVAR

• With this in mind, a closely monitored registry may reveal much more reliable results of EVAR as
  
  – Real-world patients are included
  – From real-world practices

Results may be better extrapolated to the general population
Study Purpose ENGAGE

- To prospectively collect global ‘real life’ data on the Endurant stent graft system

  - Real world patients
    - Very limited inclusion/exclusion criteria

  - Real world practice
    - Limited procedural specifications
    - Patients are followed per institution standard practices

- To create a database that can be compared with other available stent graft data
Materials and Methods

• Study Design
  – Prospective, Non Randomized, Multicenter, Closely Monitored, Single Arm Registry
    • 77 High Volume Centers Worldwide
  – Over 1200 subjects consecutively enrolled
    • First patient treated in March 2009
  – Long term Follow-up
    • 30 days, annual visits through 5 years

Unprecedented Size and Scope
ENGAGE Enrollment Distribution

- N Europe: 564
- S Europe: 182
- Canada: 119
- Middle East/Africa: 117
- Pacific: 106
- C Europe: 72
- Asia: 62
- LATAM: 40

Total: 1262; 77 sites; 30 countries
### ENGAGE Demographics

**N = 1262 Patients**

#### Baseline Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (mean)</td>
<td>73.1 ± 8.1 years</td>
</tr>
<tr>
<td>Male Gender</td>
<td>89.6%</td>
</tr>
</tbody>
</table>

#### Anatomic Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max AAA Diameter (mean)</td>
<td>60.3 ± 11.7 mm</td>
</tr>
<tr>
<td>Neck Length (mean)</td>
<td>27.0 ± 12.4 mm</td>
</tr>
<tr>
<td>Infrarenal Neck Angle (mean)</td>
<td>30.3 ± 23.8°</td>
</tr>
</tbody>
</table>

17.9% of Subjects Treated Outside of IFU Guidance
ENGAGE Demographics

N = 1262 Patients

Baseline Risk Factors

<table>
<thead>
<tr>
<th>Condition</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>SVS Risk Level 2+</td>
<td>86.3%</td>
</tr>
<tr>
<td>Hypertension</td>
<td>75.4%</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>60.4%</td>
</tr>
<tr>
<td>Tobacco Use</td>
<td>49.3%</td>
</tr>
<tr>
<td>Coronary Artery Disease</td>
<td>34.6%</td>
</tr>
<tr>
<td>Pulmonary Disease</td>
<td>25.1%</td>
</tr>
<tr>
<td>Cancer</td>
<td>20.5%</td>
</tr>
<tr>
<td>Diabetes</td>
<td>19.0%</td>
</tr>
<tr>
<td>Peripheral Vascular Disease</td>
<td>18.4%</td>
</tr>
<tr>
<td>Renal Insufficiency</td>
<td>15.3%</td>
</tr>
</tbody>
</table>
## ENGAGE Interim Analysis

### Acute Procedural Data for first 1262 Patients Enrolled

#### Baseline Characteristics

<table>
<thead>
<tr>
<th>AAA Size &gt; 50mm</th>
<th>88.1%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proximal Neck</td>
<td></td>
</tr>
<tr>
<td>Length ≤ 15 mm</td>
<td>19%</td>
</tr>
<tr>
<td>Length ≤ 10 mm</td>
<td>4.9%</td>
</tr>
</tbody>
</table>

#### Procedural Data

<table>
<thead>
<tr>
<th>Deployment Success</th>
<th>99.4%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implant Duration (median)</td>
<td>90 min</td>
</tr>
<tr>
<td>General Anesthesia</td>
<td>62.3%</td>
</tr>
<tr>
<td>Length of Stay (median)</td>
<td>5 days</td>
</tr>
</tbody>
</table>
# ENGAGE Interim Analysis

## 30 Day Follow-Up Data

### Safety Results

<table>
<thead>
<tr>
<th>Event</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>All Cause Mortality</td>
<td>1.3%</td>
</tr>
<tr>
<td>Major Adverse Events</td>
<td>4.1%</td>
</tr>
</tbody>
</table>

### Technical Results

<table>
<thead>
<tr>
<th>Event</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Migration</td>
<td>0%</td>
</tr>
<tr>
<td>Occlusion</td>
<td>2%</td>
</tr>
<tr>
<td>Endoleak</td>
<td></td>
</tr>
<tr>
<td>Type I</td>
<td>1.4%</td>
</tr>
<tr>
<td>Type III</td>
<td>0.2%</td>
</tr>
<tr>
<td>Type IV</td>
<td>0.1%</td>
</tr>
</tbody>
</table>
ENGAGE Interim Analysis (n=500)

1 Year Safety Results

**All Cause Mortality** 8.3%

**Major Adverse Events** 11.2%

- Bowel Ischemia 0.4%
- Myocardial Infarction 1.8%
- Paraplegia 0%
- Procedural Blood Loss $\geq 1000$ ml 0.6%
- Renal Failure 1.0%
- Respiratory Failure 0.2%
- Stroke 0.4%
**ENGAGE Interim Analysis (n=500)**

**1 Year Outcomes**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aneurysm Related Mortality</td>
<td>1.4%</td>
</tr>
<tr>
<td>Conversion</td>
<td>0.6%</td>
</tr>
<tr>
<td>Rupture</td>
<td>0.0%</td>
</tr>
<tr>
<td>Secondary Procedures</td>
<td>4.6%</td>
</tr>
<tr>
<td>Patency</td>
<td>97.5%</td>
</tr>
</tbody>
</table>
ENGAGE Interim Analysis at 1 Year

Type I / III Endoleak at 1 Year   0.2%

Type II Endoleak at 1 Year       8%

Migration at 1 Year              0%
ENGAGE Sac Changes at 1 Year

- 41.3% Increase
- 55.9% Stable
- 2.8% Decrease
ENGAGE Interim Analysis

Serious Adverse Device Effects (0 – 365 Days)

- Pulmonary Events: 0%
- Bleeding >1000 ml: 0.7%
- Cardiac Events: 0%
- Renal Failure: 0.7%
- Wound Events: 0%
- Gastrointestinal Events: 0%
- Vascular Events: 1.3%
- Neurologic Events: 0%
- Fever: 0.7%
Freedom from All-Cause Mortality

Frederick from All-Cause Mortality

91.6%

<table>
<thead>
<tr>
<th></th>
<th>0-30 days</th>
<th>31-365 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. at Risk¹</td>
<td>500</td>
<td>490</td>
</tr>
<tr>
<td>No. of Events</td>
<td>6</td>
<td>35</td>
</tr>
<tr>
<td>No. Censored²</td>
<td>4</td>
<td>455</td>
</tr>
<tr>
<td>Kaplan-Meier Estimate³</td>
<td>0.988</td>
<td>0.916</td>
</tr>
<tr>
<td>Beta Standard Error</td>
<td>0.005</td>
<td>0.014</td>
</tr>
</tbody>
</table>
Freedom from All-Cause Mortality

![Graph showing survival probability over time with numbers at risk for open repair and endovascular repair.](image-url)
Freedom from AAA-Related Mortality

98.6%
Freedom from Secondary Interventions

95.1%

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<thead>
<tr>
<th></th>
<th>0-30 days</th>
<th>31-365 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. at Risk¹</td>
<td>500</td>
<td>484</td>
</tr>
<tr>
<td>No. of Events</td>
<td>6</td>
<td>17</td>
</tr>
<tr>
<td>No. Censored²</td>
<td>10</td>
<td>467</td>
</tr>
<tr>
<td>Kaplan-Meier Estimate³</td>
<td>0.988</td>
<td>0.951</td>
</tr>
<tr>
<td>Peto Standard Error</td>
<td>0.005</td>
<td>0.011</td>
</tr>
</tbody>
</table>
Freedom from Secondary Interventions
Conclusion

- ENGAGE is a well-monitored registry that supplies us with data on real-world outcome after EVAR in a global series of patients.

- Results up to one year are exceptionally good.

- Long-term results have to be awaited.
Conclusion

• In contrast to a randomized trial, ENGAGE is about real-world patients in a real-world practice

• It is debatable whether randomized trials should stay “the gold standard” for evaluating treatment results
Participating Sites

Teijink (NET), Catharina Hospital
Lawlor (CAN), Victoria Hospital
van Sterkenburg (NET), Alys Zorggroep, Rijnstate Ziekenhuis
Welten (NET), Atrium Hospital
Peeters (BEL), Imelda Hospital
Boeckler (DEU), Universitätsklinikum Heidelberg
Mwipatayi (AUS), Royal Perth Hospital
Papazoglou (GRC), Kianous Stavros Clinic
Staszkiewicz (POL), Szpital Bielanski
Verhagen (NET), Erasmus Medical Centre
Goktay (TUR), Dokuz Eylul University
Riambau (ESP), Hospital Clinic i Provincial de Barcelona
Vermassen (BEL), Universitair Ziekenhuis Gent
Rand (AUT), Krankenhaus Hietzing
Bosiers (BEL), Sint Blasius Hospital
Torsello (DEU), St Franziskus Hospital GmbH
Vaquero Puerta (ESP), Hosp Clinico y Universitario de Valladolid
Wolf (ISR), Sourasky Medical Center
Fitridge (AUS), Queen Elizabeth Hospital
Salmeron (ESP), Hospital Clinico Universitario San Cecilio
Van Marle (SAF), Unitas Hospital
Do/Schmidli (CHE), Inselspital, Universitatssspital Bern
Hendriks (BEL), UZ Antwerpen
Oguskurt (TUR), Adana Baskent University Hospital
Becquemin (FRA), Hospital Henri Mondor
Hill (NZL), Auckland City Hospital
Kritpracha (THA), Songklanagarind Hospital
Punt (SAF), St Georges Hospital
Kiskinis (GRC), Papageorgiou Hospital
Novotny (CZE), Institut Klin a experimentální medicíny
Rose (GBR), Freeman Hospital
Albuquerque e Castro (POR), Centro Hosp de Lisboa
Choukroun FRA), Hop Cardiologique du Haut-Leveque
Gutowski (POL), Samodzielny Publ Szpital Kliniczny
Haggart (NZL), Waikato DHB
Numan (TUR), Memorial Hospital
De La Torra (ESP), Hosp Univ Central de Asturias
Delle (SWE), Sodersjukhuset
Dubenec (AUS), Royal Prince Alfred Hospital
Bilkis (LIT), Vilnius University Hospital
De Vries (NET), St. Antonius Hospital
Grigg (AUS), Box Hill Hospital
Grigg (AUS), Epworth Healthcare Eastern
Hayes (GBR), Addenbrookes Hospital
Hoffmann (DEU), Klinikum Solingen
Midy (FRA), Hosp Pellegrin
Palones (ESP), Hospital Universitario Dr. Peset
Mc Wiliams (GBR), Royal Liverpool Univ Hosp
Boyne (AUS), Royal Brisbane and Womens Hosp
Matley (SAF), Kingsbury Hosp
Mwipatayi (AUS), Hollywood Private Hospital