Early experience from the ENCHANT post-market registry on chEVAR with Endurant

G. Torsello
Münster
Disclosure

Speaker name: ..G.Torsello...................

I have the following potential conflicts of interest to report:

☒ Consulting
☐ Employment in industry
☐ Stockholder of a healthcare company
☐ Owner of a healthcare company
☐ Other(s)

☐ I do not have any potential conflict of interest
A study evaluating safety and effectiveness of the Endurant Chimney Graft Technique for treatment of juxtarenal aortic aneurysms with a short infrarenal neck in a real world setting.
Who is participating in ENCHANT?

14 countries
### Participating countries

**SITES & PRINCIPAL INVESTIGATORS**

<table>
<thead>
<tr>
<th>Prim. Dr. Gschwendtner</th>
<th>Dr. Seifert</th>
<th>Prof. Matsagkas</th>
</tr>
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<tbody>
<tr>
<td>Elisabethinen Linz</td>
<td>Klinikum Chemnitz</td>
<td>University Hospital of Larissa</td>
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<tr>
<th>Prof. Coscas</th>
<th>Dr. May</th>
<th>Prof. Sultan</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHU Ambroise Paré Paris</td>
<td>Krankenhaus Porz am Rhein Cologne</td>
<td>University Hospital Galway</td>
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<tr>
<th>Prof. Ducasse</th>
<th>Prof. Dr. Schmitz-Rixen</th>
<th>Prof. Mangialardi</th>
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<tbody>
<tr>
<td>CHU Bordeaux - Centre Universitaire Pellegrin Bordeaux</td>
<td>Uniklinikum Frankfurt – Goethe-Universität</td>
<td>San Camillo Hospital Rome</td>
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<thead>
<tr>
<th>Prof. Torsello</th>
<th>Prof. Böckler</th>
<th>Prof. Intrieri</th>
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<tr>
<td>St. Franziskus Hospital Münster</td>
<td>Heidelberg University Hospital</td>
<td>Cosenza Hospital</td>
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<tr>
<th>Prof. Hoffmann</th>
<th>Prof. Papazoglou</th>
<th>Prof. Celoria</th>
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<tr>
<td>Elisabeth-Krankenhaus Essen</td>
<td>Hippokratio - Thessaloniki</td>
<td>ASL 5 Hospital La Spezia</td>
</tr>
</tbody>
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Participating countries

SITES & PRINCIPAL INVESTIGATORS

Prof. Meerwaldt
Medisch Spectrum Twente
Enschede

Dr. Sikkink
Zuyderland Ziekenhuis
Heerlen

Dr. Gonçalves
Santa Marta Hospital
Lisboa

Prof. Akchurin
National Medical Research Center of Cardiology
Moscow

Dr. Vulev
CINRE Bratislava

Dr. Gimenez Gaibar
Parc Tauli Hospital
Barcelona

Dr. Resch
Skane University Hospital
Malmö

Dr. Rancic
University Hospital Zürich

Mr. Murray
Manchester Royal Infirmary

Prof. Holt
St. George's University hospitals NHS - London
PRIMARY ENDPOINTS

Safety endpoint:
• Proportion of subjects experiencing a MAE through 30 days post-index procedure

Performance endpoint:
• Technical success and freedom from secondary aneurysm-related interventions through 365 days
Secondary endpoints

Clinical success:
- Technical success
- Freedom from intra-operative death
- Freedom from endoleak Ia/III 30-days post-index procedure

Safety (up until 3 years):
- Aneurysm rupture
- Conversion to open surgery
- Aneurysm related mortality
- All-cause mortality
- MAEs
<table>
<thead>
<tr>
<th>EXCLUSION CRITERIA</th>
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<tbody>
<tr>
<td>Subject is participating in a <strong>concurrent study</strong> which may confound study results</td>
</tr>
<tr>
<td>Subject has a <strong>life expectancy ≤1 year</strong></td>
</tr>
<tr>
<td>Subject has an aneurysm that is: suprarenal or pararenal, isolated iliofemoral, mycotic, inflammatory, pseudoaneurysm</td>
</tr>
<tr>
<td>Subject requires <strong>emergent aneurysm treatment</strong>, for example, trauma or rupture</td>
</tr>
<tr>
<td>Subject has <strong>previously undergone surgical treatment for abdominal aortic aneurysm</strong></td>
</tr>
<tr>
<td>Subject is a female of childbearing potential in whom <strong>pregnancy cannot be excluded</strong></td>
</tr>
<tr>
<td>Subject has a known <strong>hypersensitivity or contraindication to anticoagulants, anti-platelets, or contrast media</strong>, which is not amenable to pre-treatment</td>
</tr>
<tr>
<td>Subject has a <strong>creatinine level &gt;2.0 mg/dl</strong> (or &gt;176.8 μmol/L) and/or is <strong>on dialysis</strong></td>
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Stents compatible for renal use with CHEVAR indication

- Atrium Advanta™ V12
- BeGraft or BeGraft+
- E-ventus BX
- Viabahn VBX

Only 6-7 mm renal stents are approved for the CHEVAR indication
CURRENT ENROLLMENT STATUS

![Graph showing enrollment status with forecast and actual data points. The graph indicates a steady increase in enrollment from October 2017 to April 2020. The actual enrollment for April 2020 is marked with a star at 49 students.]
VIDEO-CASE PRESENTATION

• Patient underwent double chimney graft placement during the ENDOVASCULAR MASTERCLASS (December 2017)
• Video starts with the intraoperative angiography showing gutter-related endoleak type IA
• Discussion in the panel about options for treatment of the gutters
CTA 12 months postoperatively
Position of the chimney graft in THE angulated LEFT renal artery
IMPROVEMENT OF THE TRANSISSION BY PLACEMENT OF A FLEXIBLE SELF-EXPANDING COVERED STENT
SMOOTH TRANSISSION AND ADVANCED COMFORMABILITY OF THE CHIMNEY GRAFT (ADVANTA PROX. + VIABAHN DISTAL)
1 MONTH POSTOPERATIVELY
CHIMNEY GRAFT OCCLUSION OF
THE LEFT RENAL ARTERY

• Flank pain for 3 days
• Patient was instead of dual antiplatelet therapy only under ASA 100mg/day due to planned operation by bladder CA
RECANALISATION AND RESTORATION OF THE BLOOD FLOW IN THE LEFT KIDNEY BY INDIGO PENUMBRA and additional placement of a balloon expandable covered stent
LEFT Kidney Function after THE Successful
FLOW RESTORATION AND REOPENING OF
THE OCCLUDED CHIMNEY GRAFT

Left kidney function 21.8%
and Creatinine Clearance 34.3 ml/min/1.73sqm
Left kidney function **12 months** after successful flow restoration and reopening of the occluded chimney graft

Left Kidney function **38.5%**

and TER Clearance **72.5 ml/min/1.73sqm**
Conclusions

• There is a lot of discussion between “believers” and “nonbelievers” in ChEVAR, which can be a successful complementary option if standardized approach is followed.

• Only a small percentage of gutters endoleaks at completion angiogram become persistent type Ia endoleaks.

• Enchant is an externally controlled post-market registry which will clarify the performance and role of this technique in the real world.
home page: www.gefaesschirurgie-muenster.de

Thank you!
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