

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

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Disclosure

Speaker name:

..G.Torsello.....

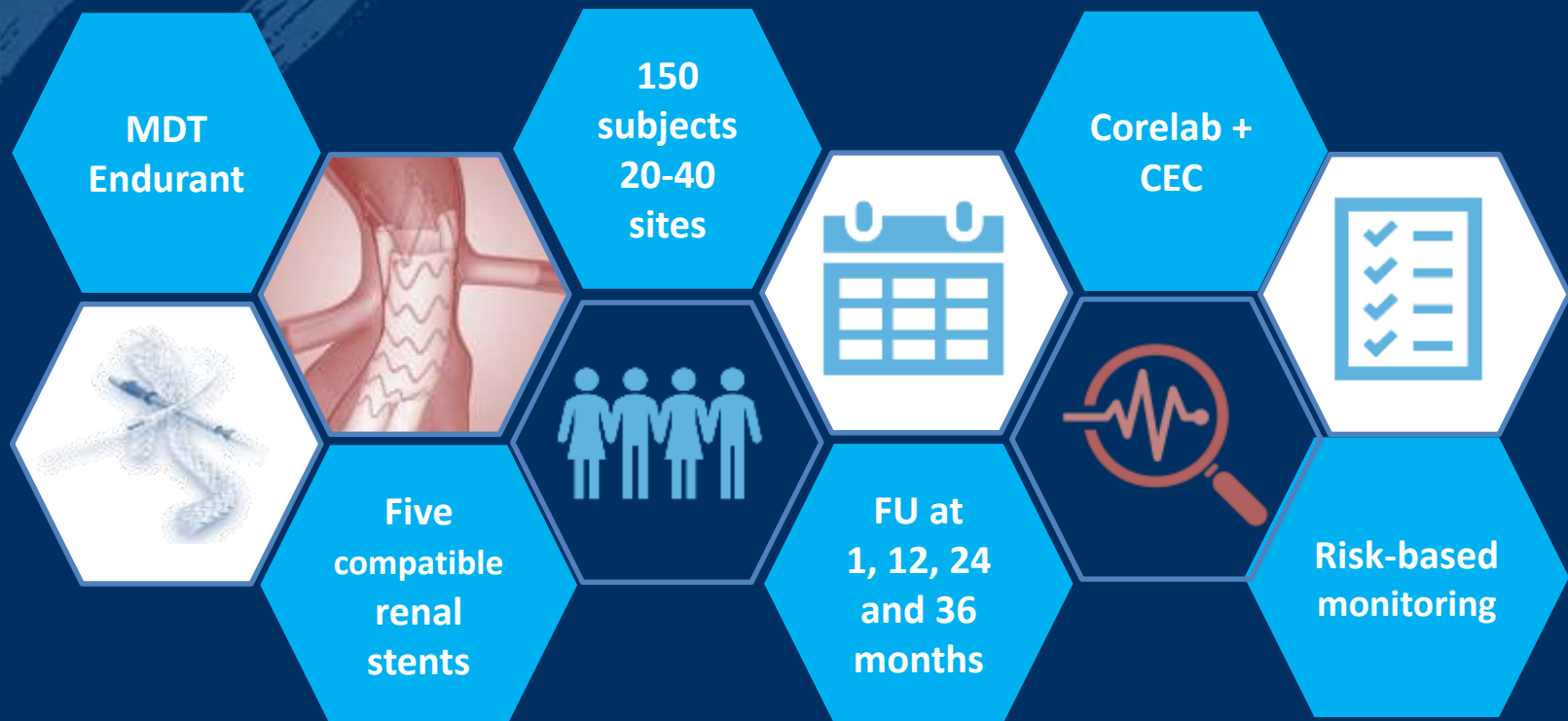
I have the following potential conflicts of interest to report:

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

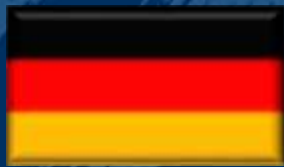
- I do not have any potential conflict of interest

ENdurant ChevAr New indication Trial: Enchant

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



Prim. Dr. Gschwendtner
Elisabethinen Linz



Dr. Seifert
Klinikum Chemnitz



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University Hospital of
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CHU Ambroise Paré
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Elisabeth-Krankenhaus
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Prof. Papazoglou
Hippokratio - Thessaloniki



Prof. Celoria
ASL 5 Hospital
La Spezia

Participating countries

SITES & PRINCIPAL INVESTIGATORS



Prof. Meerwaldt

Medisch Spectrum Twente
Enschede



Dr. Gimenez Gaibar

Parc Tauli Hospital
Barcelona



Dr. Sikkink

Zuyderland Ziekenhuis
Heerlen



Dr. Resch

Skane University Hospital
Malmö



Dr. Gonçalves

Santa Marta Hospital
Lisboa



Dr. Rancic

University Hospital Zürich



Prof. Akchurin

National Medical Research
Center of Cardiology Moscow



Mr. Murray

Manchester Royal Infirmary



Dr. Vulev

CINRE Bratislava



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

EXCLUSION CRITERIA

Subject is participating in a **concurrent study** which may confound study results

Subject has **previously undergone surgical treatment for abdominal aortic aneurysm**

Subject has a **life expectancy ≤ 1 year**

Subject is a female of childbearing potential in whom **pregnancy cannot be excluded**

Subject has an aneurysm that is: suprarenal or pararenal, isolated iliofemoral, mycotic, inflammatory, pseudoaneurysm

Subject has a known **hypersensitivity or contraindication to anticoagulants, anti-platelets, or contrast media**, which is not amenable to pre-treatment

Subject requires **emergent aneurysm treatment**, for example, trauma or rupture

Subject has a **creatinine level >2.0 mg/dl** (or >176.8 $\mu\text{mol/L}$) and/or is **on dialysis**

Stents compatible for renal use with CHEVAR indication



Atrium Advanta™
V12



BeGraft or
BeGraft+

The logo for Jotec, featuring the word "JOTEC" in a bold, orange, sans-serif font with a slight shadow effect.

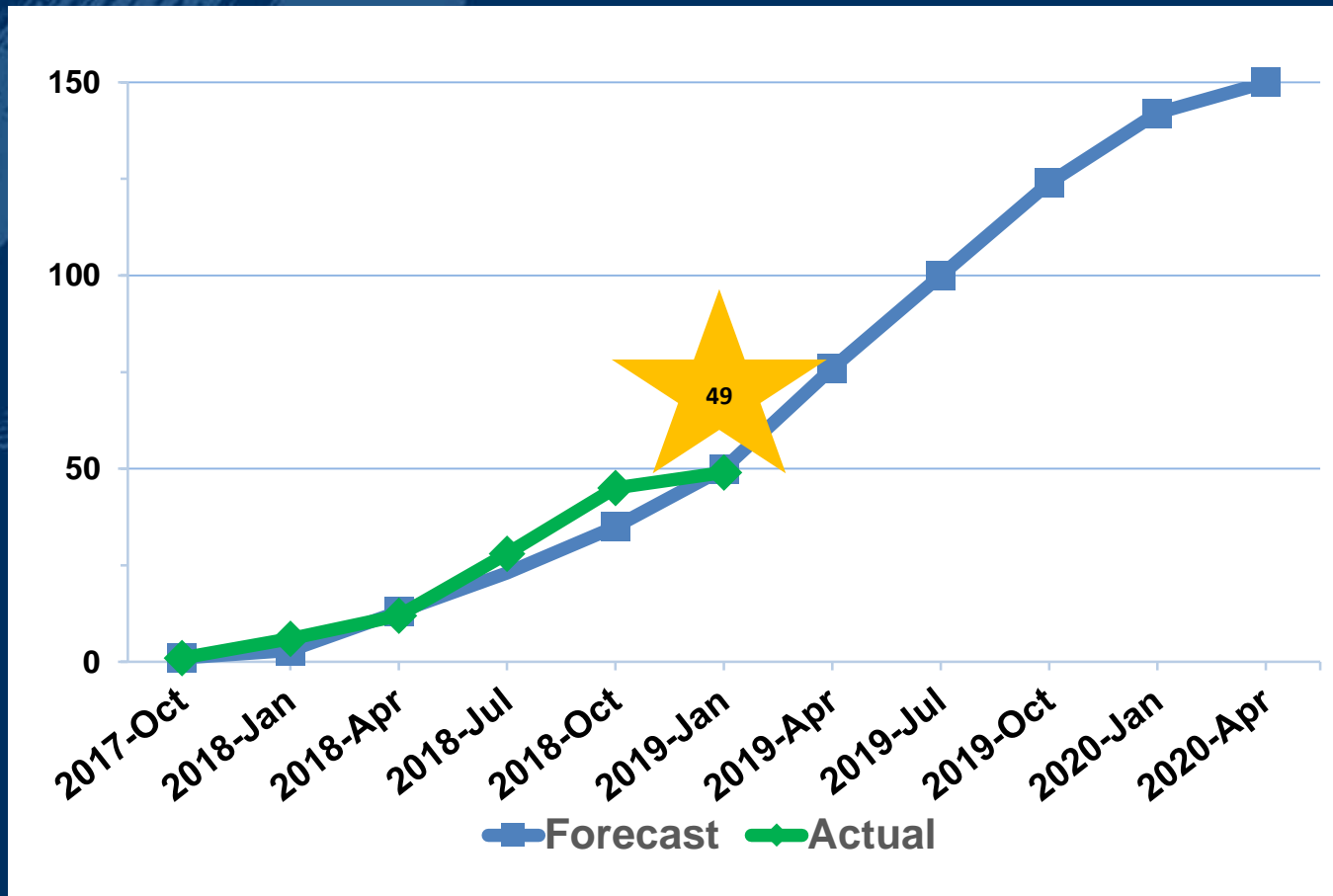
E-ventus BX



Viabahn VBX

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

CURRENT ENROLLMENT STATUS



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

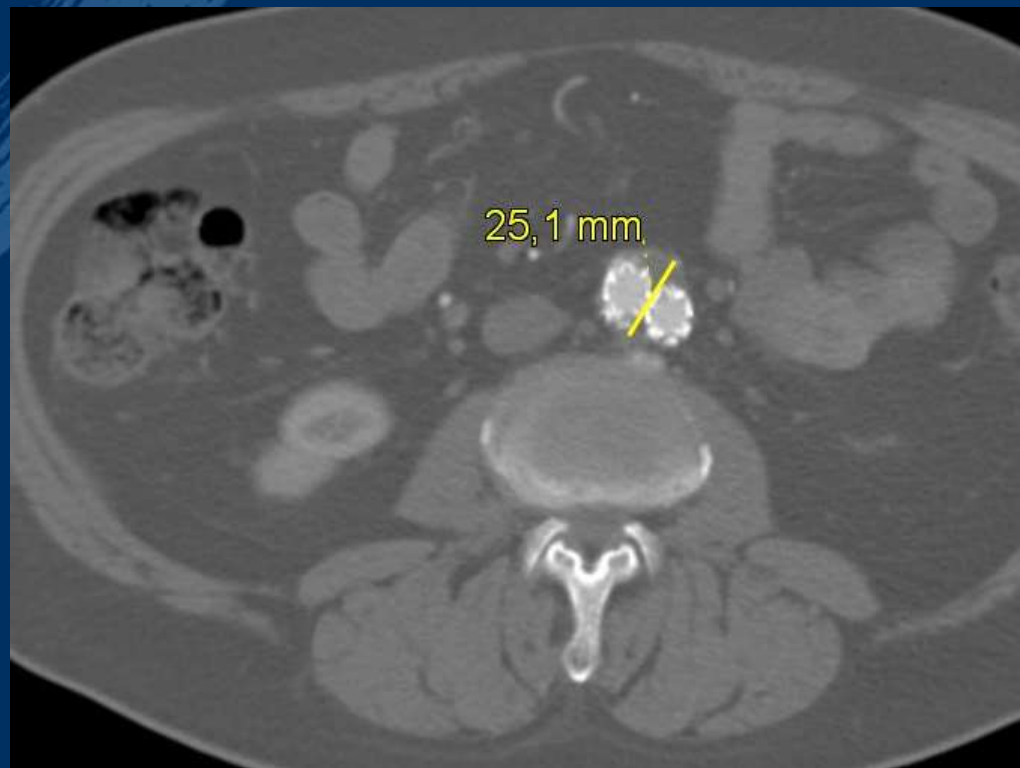
Munster

Getatschnurgle St. Franz

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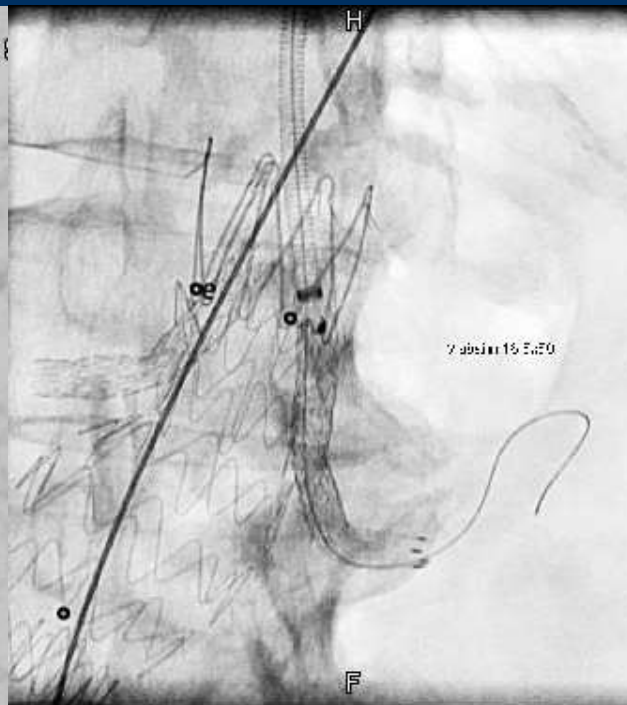
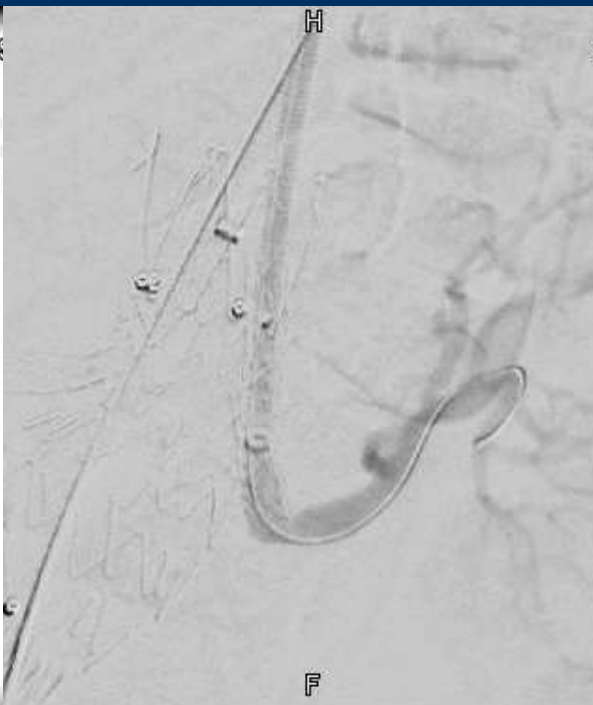
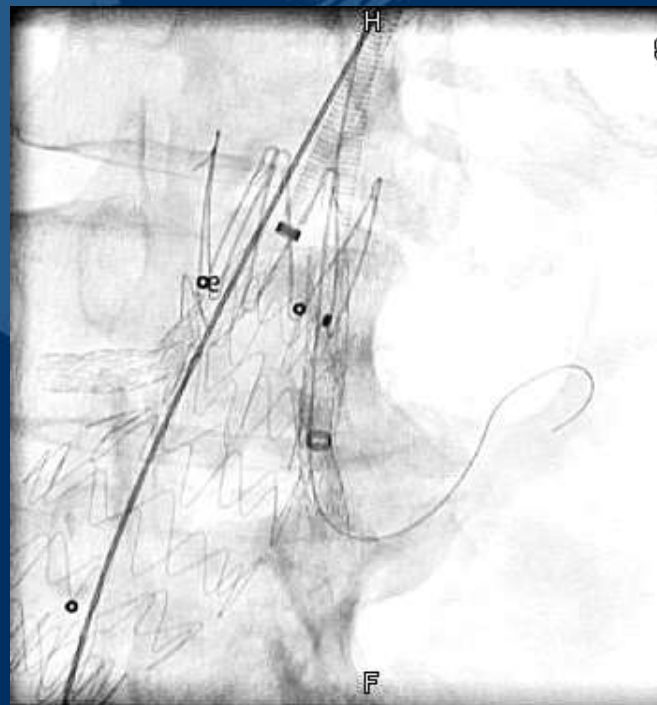
CTA 12 months postoperatively



Position of the chimney graft in THE angulated LEFT renal artery



IMPROVEMENT OF THE TRANSISSION BY PLACEMENT OF A FLEXIBLE SELF-EXPANDING COVERED STENT



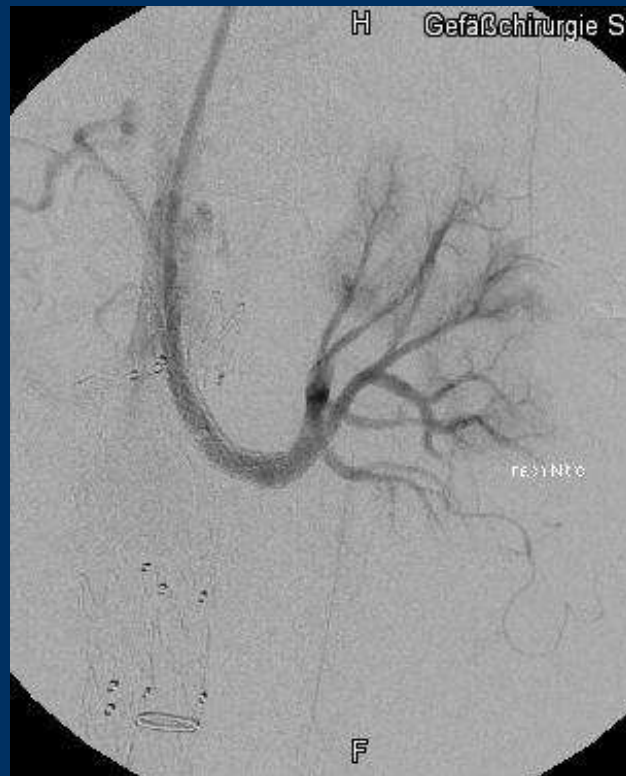
SMOOTH TRANSITION AND ADVANCED COMFORMABILITY OF THE CHIMNEY GRAFT (ADVANTA PROX. + VIABAHN DISTAL)



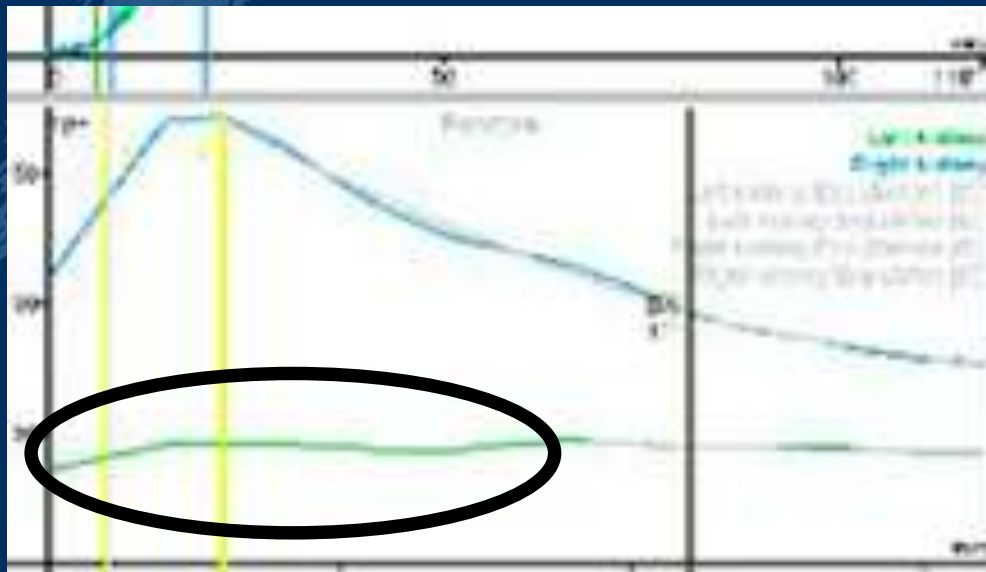
1 MONTH POSTOPERATIVELY CHIMNEY GRAFT OCCLUSION OF THE LEFT RENAL ARTERY

- 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 !



Universitätsklinik Münster



St. Franziskushospital Münster

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