Routine Post-Dilation vs. Conventional Deployment for Balloon-Expandable TAVR

The Randomized DUOTAP Trial

Maximilian Autherith, Katharina Singer, Laurenz Hauptmann, Christoph Torrefranca, Charlotte Jantsch, Sophia Koschatko, Eva-Maria Röglsperger, Kseniya Halavina, Gregor Heitzinger, Varius Dannenberg, Raghuram Palaparti, Severin Längle, Stéphane Mahr, Caglayan Demirel, Iuliana Coti, Daniel Zimpfer, Christian Hengstenberg, Christian Nitsche, Philipp E. Bartko

Medical University of Vienna, Vienna, Austria

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Disclosure of Relevant Financial Relationships

I, Maximilian Autherith do not have any financial relationships to disclose.

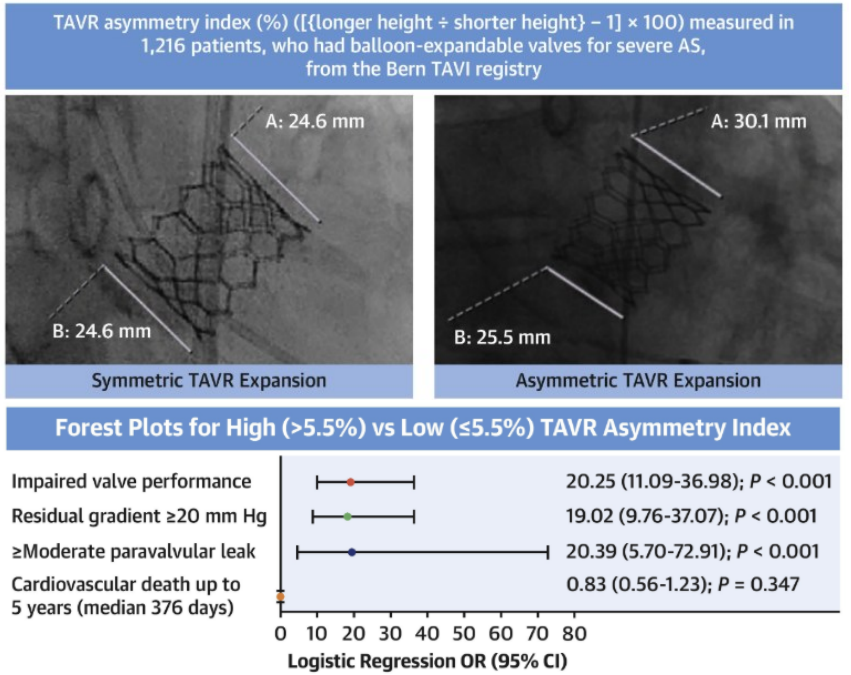
Background

Focus shift: Procedural success alone

→ THV hemodynamics, durability and lifetime management

Asymmetric THV expansion:

- Higher residual gradients
- Paravalvular leak
- Impaired THV performance



Maznycka et. al. JACC Int. 2024

New interventional treatment target: Optimization of THV geometry

Background

Post-dilatation

(original delivery balloon at the identical filling volume)

Benefits:

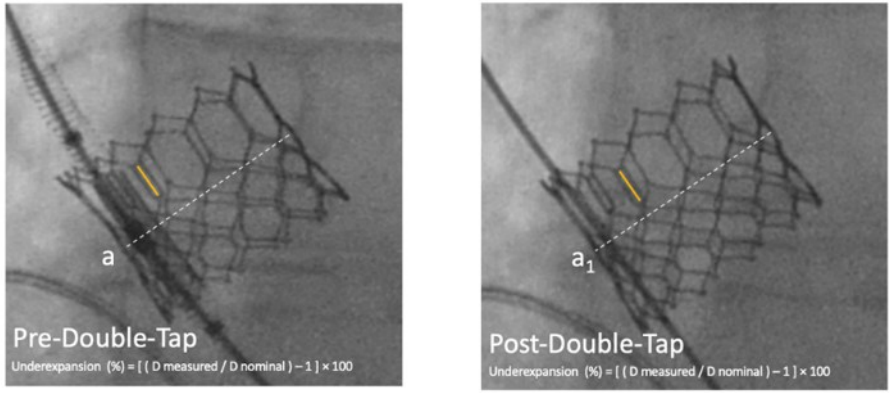
- Improves THV expansion

Concerns:

- Risk of procedural complications

Limitations:

- Retrospective and observational studies
- No randomized control group



Jelisejevas et. al. JACC Int. 2026

No randomized controlled data on efficacy and safety of post-dilatation

Methods

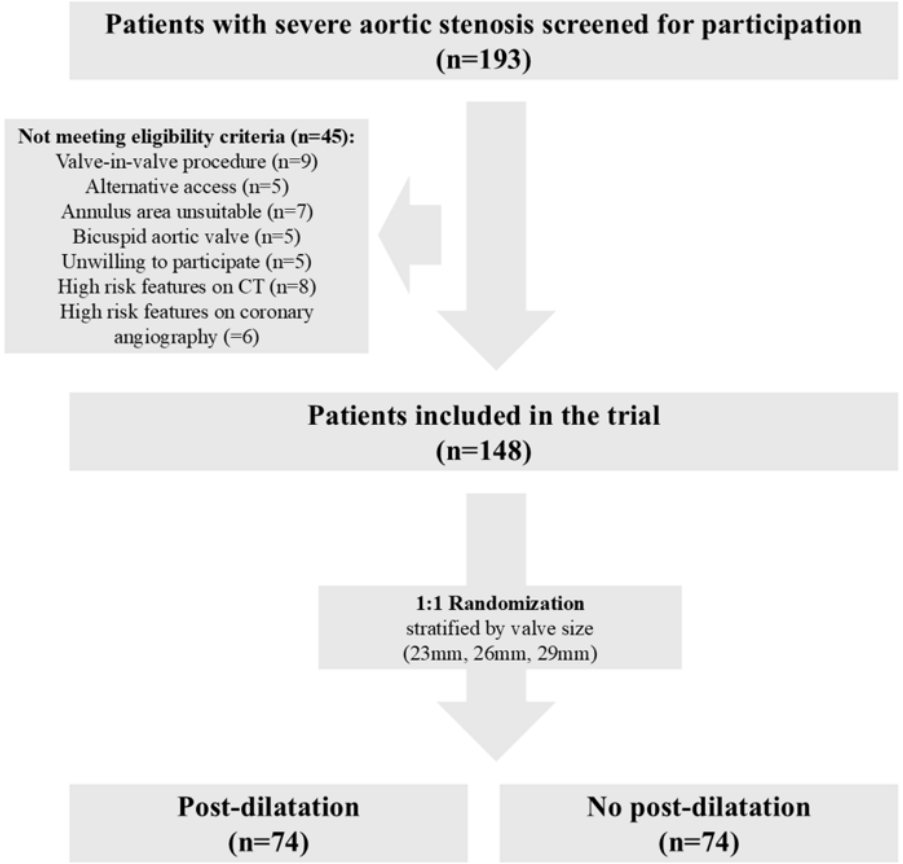
DUOTAP

prospective, single-center, single-blinded, randomized controlled trial

- **Recruitment:** 01/2025 to 04/2026 at the Medical University of Vienna
- **Severe AS** undergoing **transfemoral TAVI with a balloon-expandable THV**
- **Free from adverse features** on preprocedural CTA and/or ICA
- **Power calculation: n=148 patients**

  -0.75 units in the THV asymmetry index

  -20% impaired THV performance



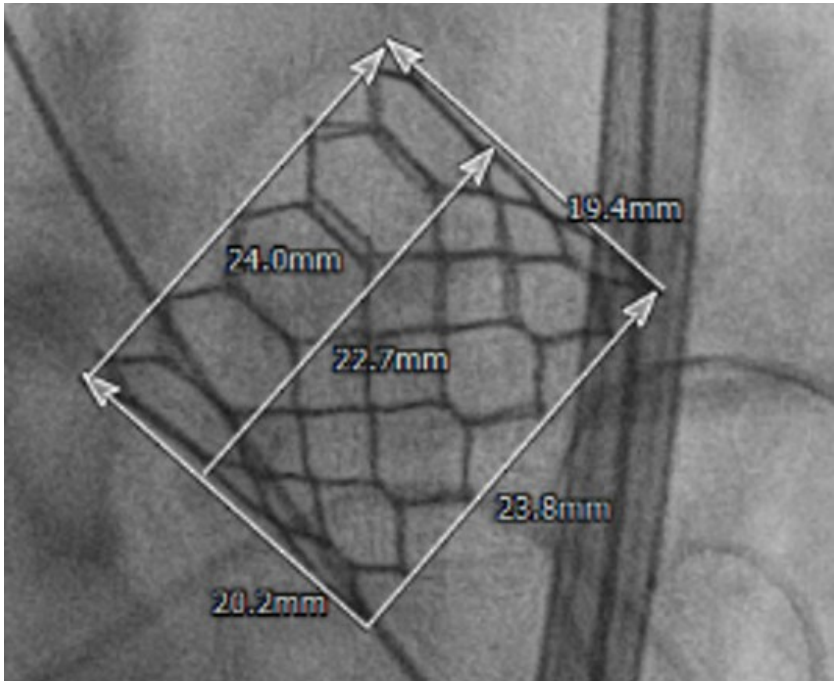
Trial Endpoints

Primary Endpoint:

- **THV asymmetry index** on fluoroscopy

Secondary Endpoints:

- **THV heights and diameters** on fluoroscopy
- **THV areas** on CT
- **Hypo-attenuated leaflet thickening** on CT
- **THV hemodynamics** (residual mPG and DVI) on echocardiography
- **≥mild paravalvular leak** on echocardiography
- Procedural and early clinical **adverse events** at 30 days



Baseline and procedural characteristics

Demographics:

- Age: 81 (77-85) years
- Sex: 46.6% (n=69) female
- EuroScore-II: 2.3% (1.7-3.3)

THV sizes:

- ES 23mm: 29.0% (n=43)
- ES 26mm: 48.7% (n=72)
- ES 29mm: 22.3% (n=33)

THV technologies:

- Resilia tissue: 42.6% (n=63)
- Non-resilia tissue: 57.4% (n=85)

	Intervention (n=74)	Control (n=74)
Age, y	81 (77-84)	82 (78-85)
Female, n (%)	34 (45.9)	35 (47.3)
Diabetes, n (%)	29 (39.2)	22 (29.7)
Atrial fibrillation, n (%)	25 (33.8)	22 (29.7)
CAD, n (%)	31 (41.9)	42 (56.8)
Prior pacemaker, n (%)	7 (9.5)	10 (13.5)
EuroScore-II, %	2.3 (1.9-3.2)	2.1 (1.6-3.3)
NT-proBNP, pg/ml	930 (430-1,776)	751 (366-1,568)
eGFR, ml/min/m^2	65 (47-87)	63 (48-77)
NYHA I, n (%)	7 (9.5)	17 (23.0)
NYHA II, n (%)	39 (52.7)	30 (40.5)
NYHA III, n (%)	26 (35.1)	26 (35.1)
NYHA IV, n (%)	2 (2.7)	1 (1.4)
AV MPG, mmHg	44 (36-48)	42 (38-52)
AV Vmax, m/s	4.2 (4.0-4.5)	4.2 (4.0-4.6)
AV orifice area, cm^2	0.7 (0.6-0.8)	0.7 (0.6-0.9)
LVEF, %	55 (51-58)	55 (48-57)

Results - primary endpoint

Post-dilatation:

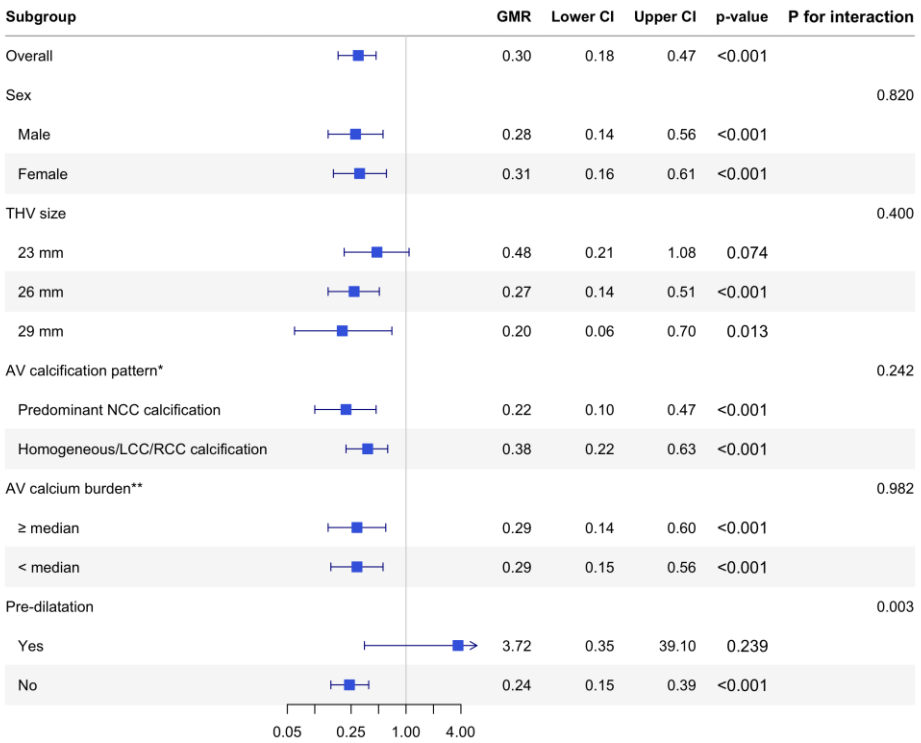
- **-70% THV asymmetry index**

  in the overall population

  (1.2% [0.5-2.4] vs. 2.8% [1.8-5.1])

- **Consistent effects across pre-specified subgroups:**

  Sex, THV size, THV technology, AV calcification pattern and overall calcium burden



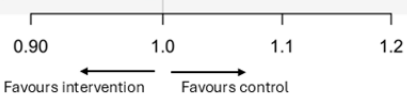
Results - secondary fluoroscopic endpoints

Post-dilatation:

- **-3%** valve height across the outer curve of the THV
- **+3%** larger THV diameters at the inflow, midframe and outflow level

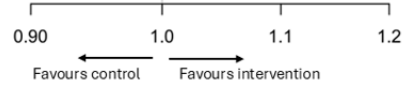
A Transcatheter heart valve height (fluoroscopy)

	GMR	Lower CI	Upper CI	p-value
Outer curve height	0.97	0.94	1.00	0.025
Inner curve height	0.99	0.96	1.01	0.352



B Transcatheter heart valve diameter (fluoroscopy)

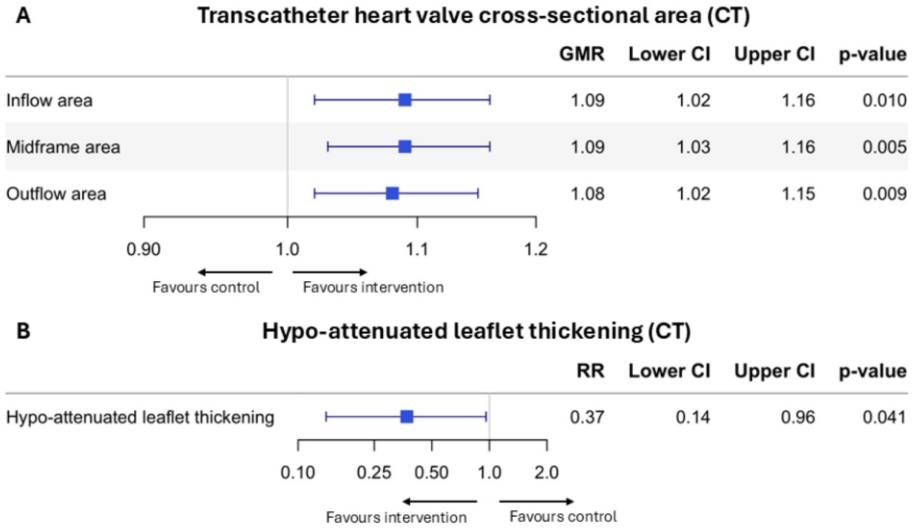
	GMR	Lower CI	Upper CI	p-value
Inflow diameter	1.03	1.00	1.06	0.076
Midframe diameter	1.03	1.00	1.06	0.062
Outflow diameter	1.03	1.00	1.06	0.064



Results - secondary CT-derived endpoints

Post-dilatation:

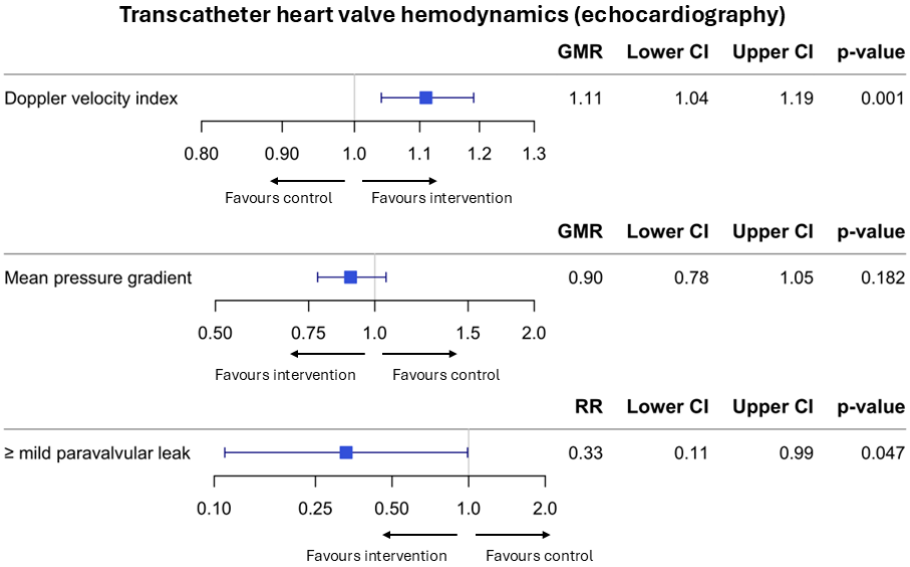
- **+9%** larger inflow and midframe cross-sectional THV area
- **+8%** larger outflow cross-sectional THV area
- **-63%** risk for hypo-attenuated leaflet thickening
  (5 [8.3%] vs. 13 [22.8%])



Results - secondary hemodynamic endpoints

Post-dilatation:

- **+11%** Doppler velocity index (0.57 ([0.51-0.67] vs. 0.52 [0.46-0.59])
- **-10%** residual trans-prosthetic gradient (9.0mmHg [6.0-11.5] vs. 9.0mmHg [7.0-13.0])
- **-67%** risk for ≥mild paravalvular leak (4 [5.4%] vs. 12 [16.2%])



Results - secondary safety endpoints

No increase in procedural or early clinical adverse events at 30 days

- Any complication: **p=0.36**
- Separate complications: **all p>0.35**

	Intervention (n=74)	Control (n=74)
Any complication, n (%)	18 (24.3)	23 (31.1)
All-cause mortality, n (%)	1 (1.4)	2 (2.7)
Any type of stroke, n (%)	2 (2.7)	1 (1.4)
Procedure- or valve-related hospitalization, n (%)	0 (0.0)	1 (1.4)
Type ≥2 bleeding, n (%)	1 (1.4)	2 (2.7)
Major vascular complication, n (%)	1 (1.4)	4 (5.4)
Major cardiac structural complication, n %	1 (1.4)	1 (1.4)
New conduction system disorder requiring pacemaker implantation, n (%)	15 (20.3)	16 (21.6)
Valve-in-valve implantation, n (%)	0 (0.0)	2 (2.7)

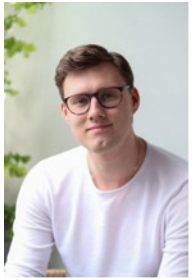
Conclusions

DUOTAP - first randomized controlled trial:

- **Post-dilatation improved THV asymmetry**
- **Optimized THV geometry**
  - **Improved THV hemodynamics**
  - **Lower** prevalence of **hypo-attenuated leaflet thickening** and **paravalvular leak** ⇩
- **Procedural adverse events** ⊥

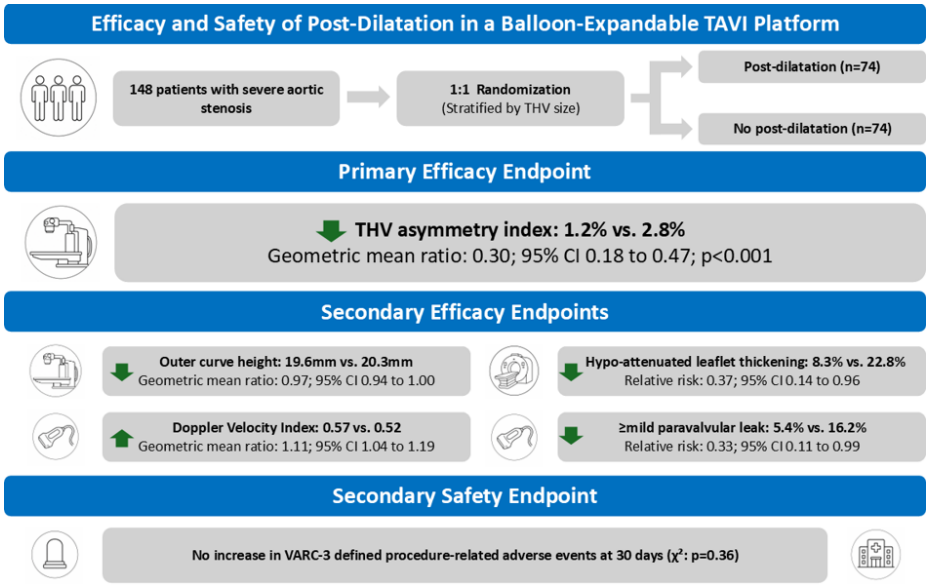
Future direction:

- **Clinical long-term outcomes?**

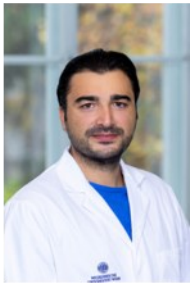





Thank you for your attention!





maximilian.autherith@meduniwien.ac.at
christian.nitsche@meduniwien.ac.at
philippemanuel.bartko@meduniwien.ac.at



MEDIZINISCHE UNIVERSITÄT WIEN

Wiener Gesundheitsverbund
Universitätsklinikum AKH Wien

Für die Stadt Wien