

# **Immediate Clinical Outcomes, Hemodynamic Performance, and Leaflet Thrombosis Following Transcatheter Aortic Valve Replacement with the Latest Intra-Annular Devices**

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# Disclosure

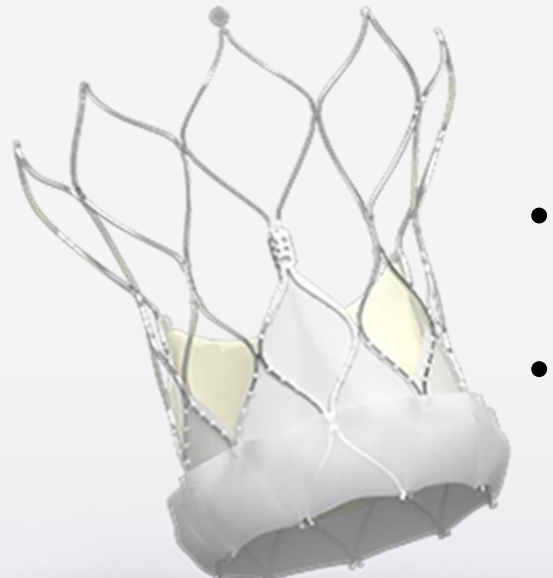
- I do not have any potential conflict of interest to declare

# Shifting toward younger and lower-risk patients

- There remains a paucity of data regarding the latest intra-annular TAVR devices that preserve better coronary access
- Currently available intra-annular TAVR devices in Japan;  
**SAPIEN 3 Ultra RESILIA (S3UR) and Navitor**



- Ultra skirt  
>> reduce PVL
- RESILIA tissue  
>> improve durability



- NaviSeal  
>> reduce PVL
- FlexNav  
>> improve accessibility

# Short-term clinical outcomes including MDCT analysis

- May 2022 to October 2023
- Keio University Hospital
- Post-procedural MDCT to evaluate HALT

286 patients with severe AS who underwent TAVR enrolled

- 151 patients Evolut Pro+ or Evolut FX or Sapien 3
  - 4 TAV in TAV
  - 2 TAV in SAV
  - 2 involved in the other clinical trial
  - 26 with missing data for MDCT
  - 4 with missing data for TTE or poor-quality MDCT

97 analytic cohort

53 patients with SAPIEN 3 Ultra RESILIA

44 patients with Navitor

# Baseline characteristics

MDCT variables	S3UR	Navitor	
area, mm <sup>2</sup>	387 [362-455]	356 [317-405]	0.007
perimeter, mm	71.1 [69.2-76.9]	67.9 [65.0-72.4]	0.008
MLD of right iliofemoral access, mm	6.3 [5.7-7.0]	6.0 [4.9-6.5]	0.042
MLD of left iliofemoral access, mm	6.0 [5.5-6.7]	5.5 [4.9-6.2]	0.047

- Basic characteristics were similar except for hemodialysis (S3UR vs. Navitor; 20.8 % vs. 0 %, p=0.001)
- Age 86 [81-89], Male 29.9%
- Annulus area; Navitor < S3UR
- Access vascular diameter; Navitor < S3UR

# Procedural characteristics

	<b>S3UR</b>	<b>Navitor</b>	
VARC-technical success	53 (100)	44 (100)	1
mean pressure gradient mmHg	5.1 [3.4-7.7]	5.3 [3.2-7.9]	0.986
new PMI after the procedure	3 (5.7)	12 (27.3)	0.003

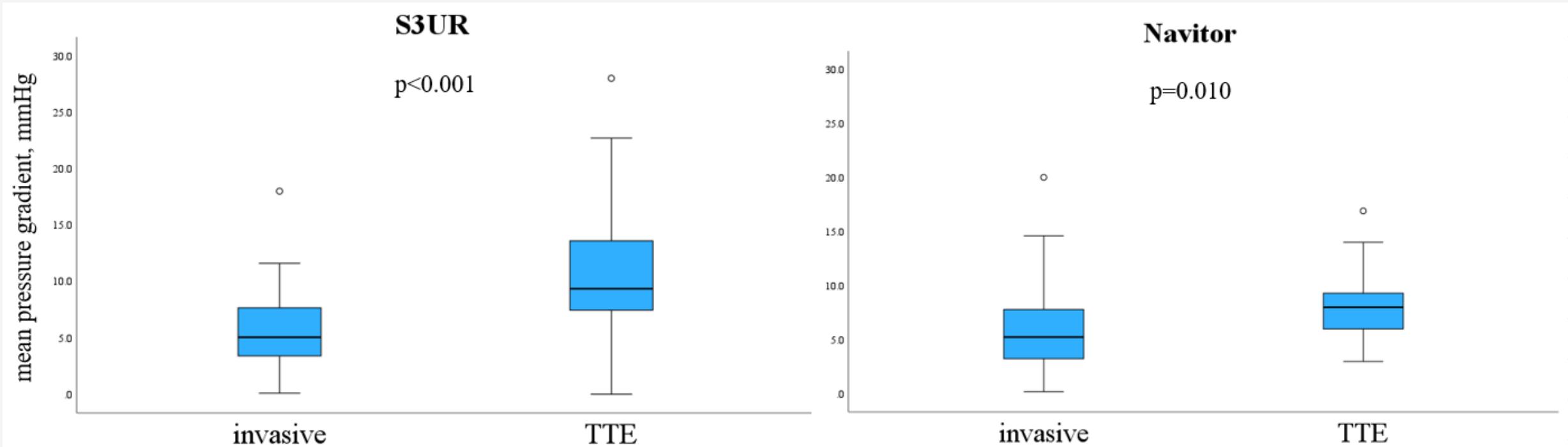
- Technical success was excellent
- Invasive measurements; S3UR = Navitor
- Permanent pacemaker implantation was more frequently required with Navitor than with S3UR

# Post-TAVR echocardiographic outcomes

	<b>S3UR</b>	<b>Navitor</b>	
THV Vmax, m/s	2.1 [1.9-2.7]	2.0 [1.7-2.3]	0.016
mean pressure gradient, mmHg	9.2 [7.3-13.6]	7.5 [5.9-9.5]	<b>0.006</b>
PPM			
no PPM	42 (79.2)	41 (93.2)	
moderate PPM	10 (18.9)	1 (2.3)	
severe PPM	1 (1.9)	2 (4.5)	<b>0.085</b>
PVL			
none or trivial PVL	40 (75.5)	20 (45.5)	-
mild PVL	13 (24.5)	24 (54.5)	-
moderate or severe PVL	0 (0)	0 (0)	<b>0.002</b>

- Hemodynamic assessment; S3UR < Navitor
- mild PVL; S3UR < Navitor, none of moderate PVL

# Discordance: invasive vs. echocardiographic measurement



- More prominent with S3UR (balloon-expandable) than with Navitor (self-expandable)



# HALT with MDCT analysis

	<b>S3UR</b>	<b>Navitor</b>	
	n= 53	n= 44	p
<b>HALT</b>	<b>12 (22.6)</b>	<b>16 (36.4)</b>	<b>0.138</b>
HALT <grade 2	10 (18.9)	13 (29.5)	0.329
HALT >grade 3	2 (3.8)	3 (6.8)	
HALT with NCC leaflet	3 (5.7)	1 (2.3)	0.118
HALT with RCC leaflet	3 (5.7)	7 (15.9)	
HALT with LCC leaflet	0 (0)	3 (6.8)	
HALT with multi leaflet	6 (11.3)	5 (11.4)	

- Statistically comparable incidence of HALT (28.9%)
- Comparing with and without HALT, there were no differences in hemodynamic assessments

# The essential results

- VARC-defined technical success was completely achieved in both S3UR and Navitor
- Despite smaller annulus, Navitor demonstrated better post-procedural hemodynamic performance with TTE than S3UR
- Discordance was more prominent with S3UR than Navitor
- Mild PVL was more frequent with Navitor, despite no moderate-severe PVL in each group
- The incidence of HALT was about 30% in total and was comparable in the two groups

# Discussion

- There was a high incidence of HALT with the latest valves  
MDCT analysis should be useful for detecting HALT earlier
- Significant discordance was observed in both valves  
Invasive hemodynamic measurement during the procedure is important
- Both the latest valves demonstrated excellent hemodynamic performance with minimal PVL and technical success after TAVR  
We should use both devices according to the characteristics of each patient

# Conclusion

- Comparing short-term clinical outcomes between S3UR and Navitor
- Device technical success was excellent
- Both valves demonstrated excellent hemodynamic performance
- Discordance was prominent with both valves
- The incidence of HALT was high and comparable in both groups