ReTAVI Registry

Early Outcomes of Redo-TAVI with SAPIEN Platform in a Real-World Prospective Cohort

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Disclosure of Relevant Financial Relationships

Within the prior 24 months, I have had a financial relationship with a company producing, marketing, selling, re-selling, or distributing healthcare products used by or on patients:

Nature of Financial Relationship	Ineligible Company
Consultant Fees/Honoraria	Abbott Laboratories, Boston Scientific, Edwards Lifesciences, Medtronic, GADA, Microport, SMT

All relevant financial relationships have been mitigated.
Faculty disclosure information can be found on the app

Background

- ***TAVR is increasingly adopted in younger, lower-risk patients with longer life expectancy. As its use broadens, the incidence of THV failure is expected to increase.***

- ***Redo-TAVR has become the preferred treatment for failed THVs due to lower procedural risk than surgical explantation, but current evidence is mainly retrospective*** [1-2].

Objectives

To prospectively evaluate real-world procedural and 30-day outcomes of redo-TAVR using a balloon-expandable valve from the SAPIEN THV family.

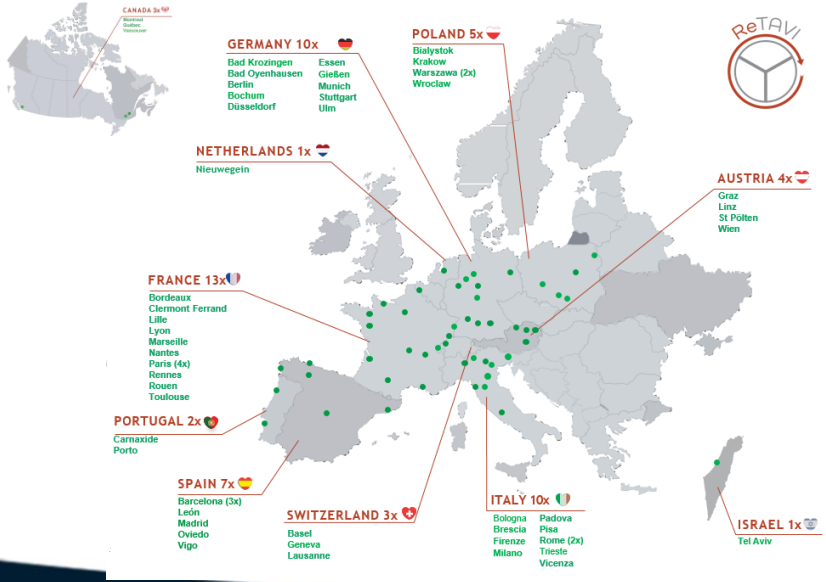
1. Landes U et al, JACC 2020;75:1882-1893.
2. Schmidt T et al, EuroIntervention 2016;12:875-882.

Study organization

ReTAVI

Principal Investigators: *Giuseppe Tarantini (Italy), Radoslaw Parma (Poland)*

59 European and Canadian Centers



- ***Steering Committee:***
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  - *Prof. Victoria Delgado, ES*
  - *Prof. Michael Joner, DE*
  - *Prof. Thomas Modine, FR*
  - *Prof. Francesco Saia, IT*
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  - *Dr. Matthias Eden, DE*
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- ***Sponsor:***
  - *IPPMED GmbH, DE*

Materials and Methods # 1

Prospective, investigator-initiated, international, multicenter registry (clinicaltrials.gov ID: NCT05601453)

INCLUSION CRITERIA:

- ***Patients undergoing redo-TAVR with a balloon-expandable SAPIEN THV after failure of the index THV, regardless of initial valve type.***
- ***Prior successful TAVR with indication for redo-TAVR confirmed by the local Heart Team.***

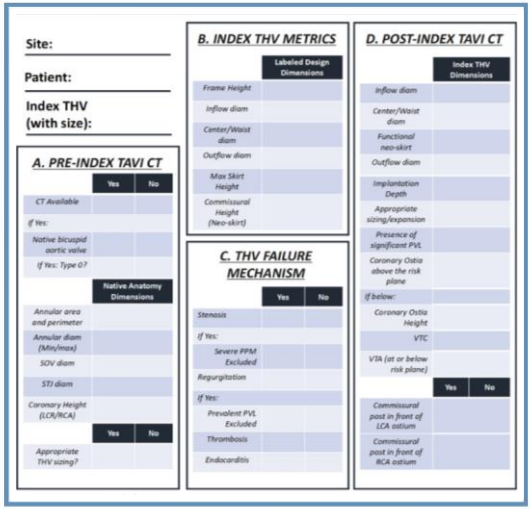
EXCLUSION CRITERIA:

- ***Life expectancy < 12 months, pregnancy, inability to provide consent***

PRIMARY ENDPOINT: VARC-3 device success and freedom from major complications at 30 days (CEC adjudication and Independent Corelab)

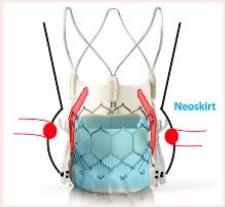
Materials and Methods #2

Pre-procedural planning



Based on previously published consensus document[1]

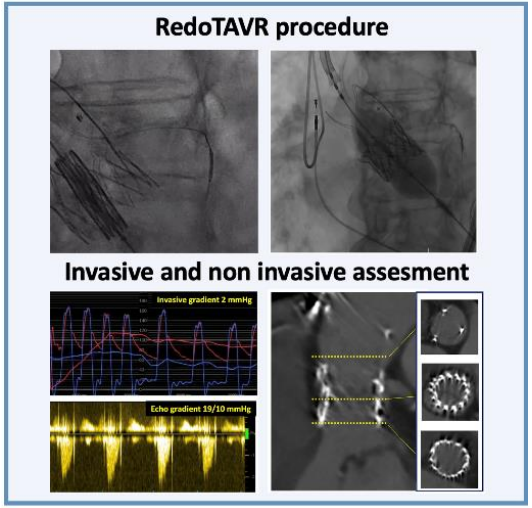
CRB evaluation and counseling



Sapien 3 Ultra 26 mm
Low implantation
Coronary protection

Case review board counseling

RedoTAVR procedure and follow up



Independent Corelab and Clinical Event Commitee

1. Tarantini G et al, AJC 2023;192:228-244.

Results #1 : Baseline pts characteristics

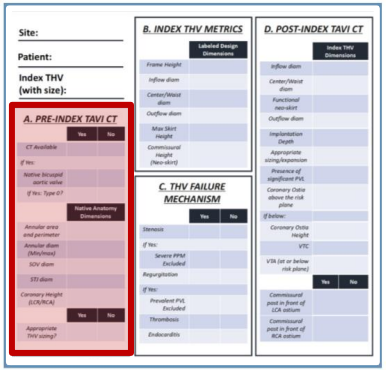
143 patients enrolled between September 2023 and July 2025

	N = 143
Sex, female	40.6%
Age, years	84
STS risk score	7.0%
Diabetes	27.3%
Arterial hypertension	79.7%
CKD / Dialysis	27.3%
Prior PCI	37.3%
LVEF	55.0%
NYHA III/IV	62.9%

Chronic kidney disease, CKD; left ventricular ejection fraction, LVEF; New York Heart Association, NYHA; percutaneous coronary intervention, PCI; Society of Thoracic Surgeons, STS

Results #2 : (Native valve) CT scan analysis

Pre-procedural planning



	Total N = 143	SAPIEN N = 43	CV/ Evolut N = 76	ACURATE N = 20	Others N = 4
Annulus area, mm²	480	***459***	***519***	***452***	398
Bicuspid aortic valve	15%	*20%*	18%	7%	0%
STJ Diameter	29.6	27.5	***31.0***	31.4	29.6
LCA height	12	13	12	11	14
RCA height	16	16	16	15	17

How about failed supra-annular THVs in small annuli?
More often to TAVR explantation?

Results #3 : THV failure mechanism (*SVD >90%*)

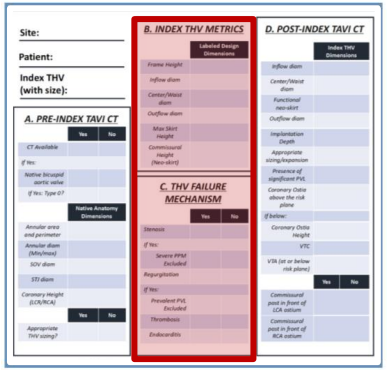
SAPIEN *(30.1%)* 

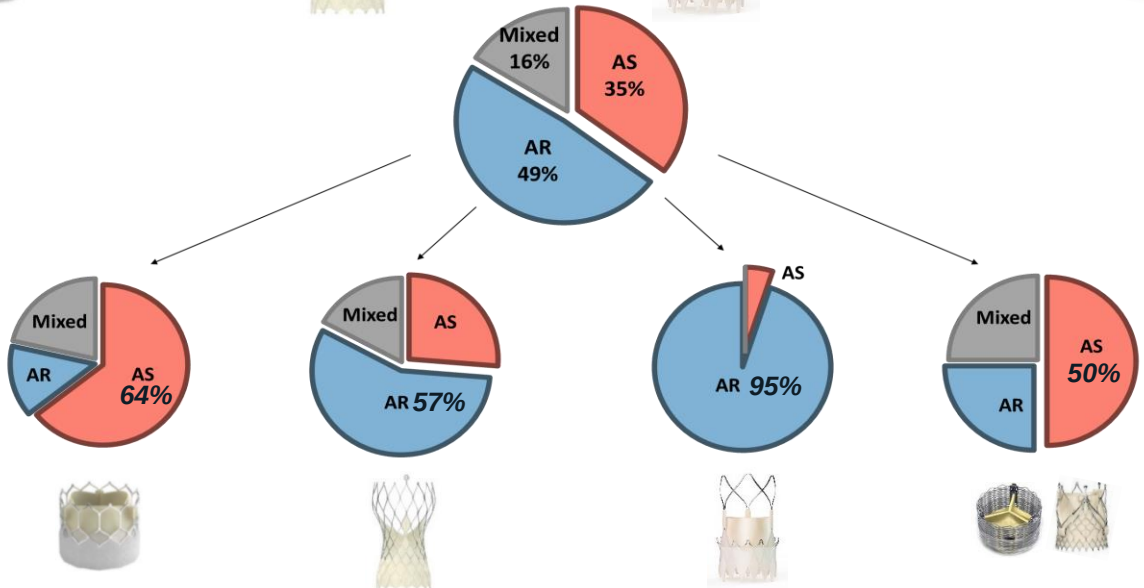
CV/Evolut *(53.1%)* 

Acurate *(14.0%)* 

Others *(2.8%)* 

Pre-procedural planning





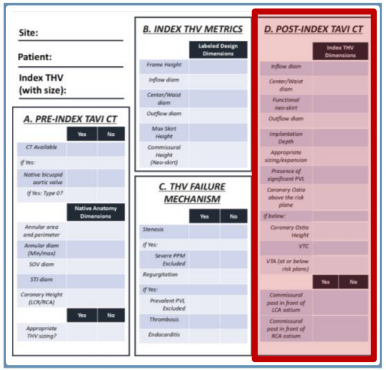
7.1 yrs ***5.9 yrs*** ***5.6 yrs***

Mean time to reintervention

Structural Valve Deterioration, SVD; Transcatheter Heart Valve, THV

Results #4 : CT scan of the failed THV

Pre-procedural planning



	Total N = 143	SAPIEN N = 43	CV/ Evolut N = 76	ACURATE N = 20	Others N = 4
THV waist diameter	23	23	22	23	23
THV inflow diameter	24	24	24	24	22
Implant depth	4.1	3.6	5.0	5.0	3.3
Risk plane height, mm	18	16	18	20	15
Supracoronary Risk plane	84%	76%	88%	90%	50
LCA VTC, mm	6.0	5.1	6.6	5.9	6.6
RCA VTC, mm	5.2	4.1	5.4	6.0	5.2
LCA VTA, mm	3.2	1.5	3.3	3.5	7.2
RCA VTA, mm	3.0	1.2	3.2	2.2	3.4

Risk Plane, RP; Transcatheter Heart Valve, THV; valve to coronary distance, VTC; valve to aorta distance, VTA; left coronary artery, LCA; right coronary artery, RCA

Results #5 : Re-do TAVR procedure

	N = 143
Implanted THV	
SAPIEN 3	20.3%
SAPIEN 3 Ultra	69.2%
SAPIEN 3 Ultra Resilia	10.5%
Implanted THV size	
20 mm	8.4%
23 mm	*39.2%*
26 mm	*44.8%*
29 mm	7.7%
Transfemoral access	98.6%
THV predilation	*17.0%*
Redo-THV post-dilatation*	*24.5%*
Coronary protection	26.2%
Final chimney stenting/BASILICA	17.9%

** Intraprocedural evaluation of final gradient was mandatory*

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	Short frame THVs (n=46)	Tall frame THVs (n=97)
Same size	58.7%	58.4%
Downsizing*	41.3%	39.6%
Upsizing	0.0	1.0%

*One size below nominal index THV size for short-frame THVs, two sizes below nominal index THV size for tall-frame THVs

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Upsizing	0.0	1.0%

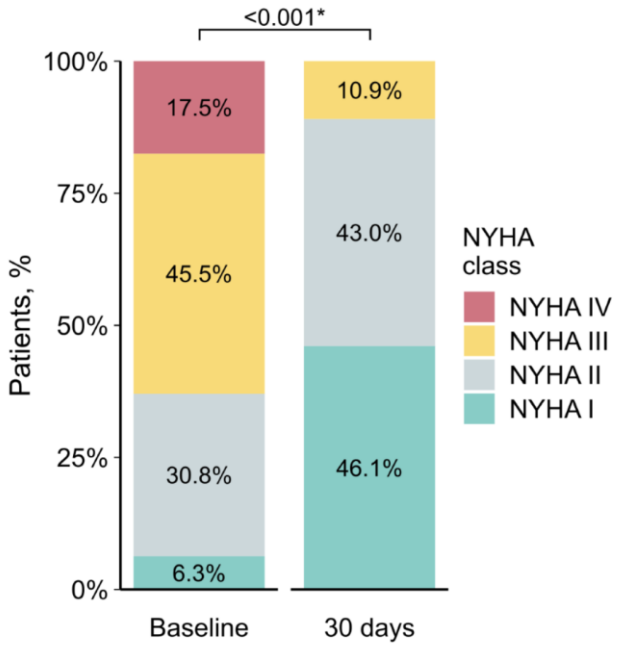
	Short frame THVs (n=46)	Tall frame THVs (n=97)
Coronary protection	22%	28%
Final chimney stenting/BAS.	15%	19%

*One size below nominal index THV size for short-frame THVs, two sizes below nominal index THV size for tall-frame THVs

Results #6 : 30-day Clinical Outcomes

	Discharge	30 days
VARC-3 device success	-	**95%**
All-cause mortality	3.5%	**3.5%**
Cardiovascular mortality	3.5%	3.5%
Stroke/TIA	0.0%*	**0.7%**
Coronary obstruction	1.4%	1.4%
PM implantation	5.6%	**6.3%**
AKI, stage 3-4	2.1%	2.8%
VARC-3 ≥2 bleeding	4.2%	4.9%
THV thrombosis	0.0%	0.0%
Endocarditis	0.0%	0.0%

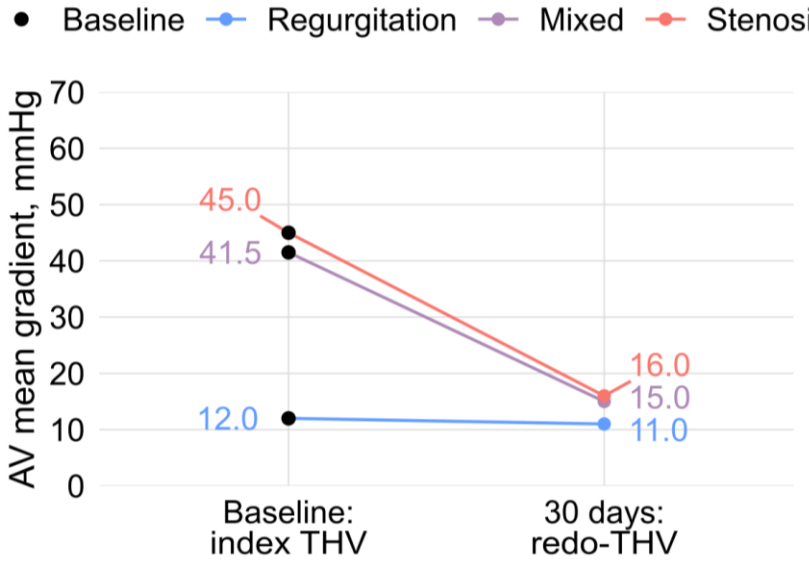
NYHA class change



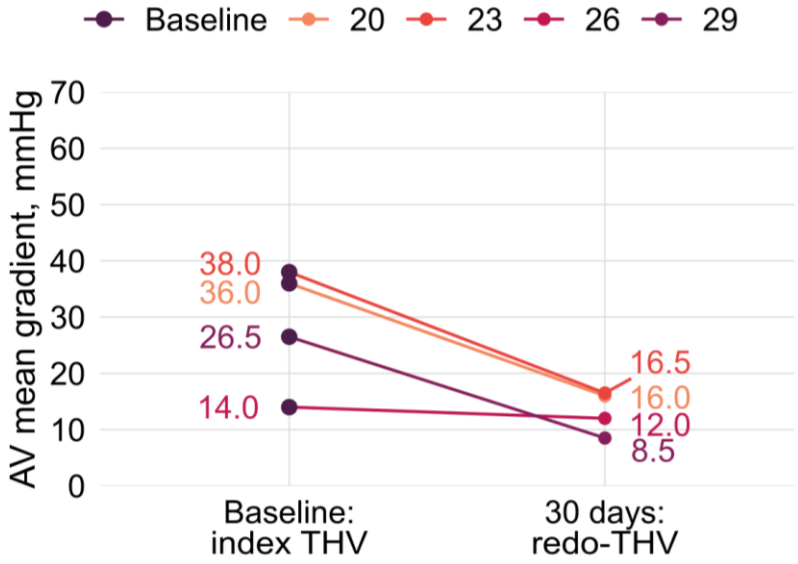
** Cerebral Embolic Protection in 10.7% of patients*

Results #7 : THV Performance (Echo)

Stratified by index THV failure mechanism



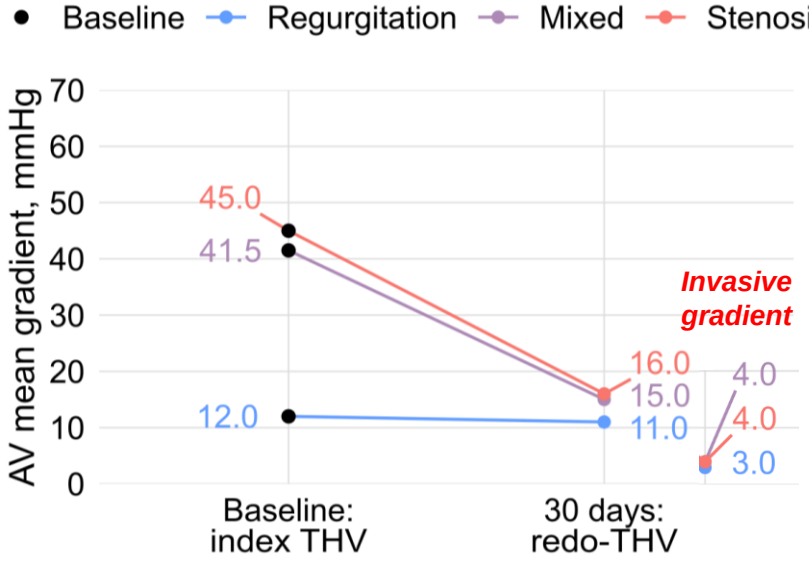
Stratified by Redo-THV size



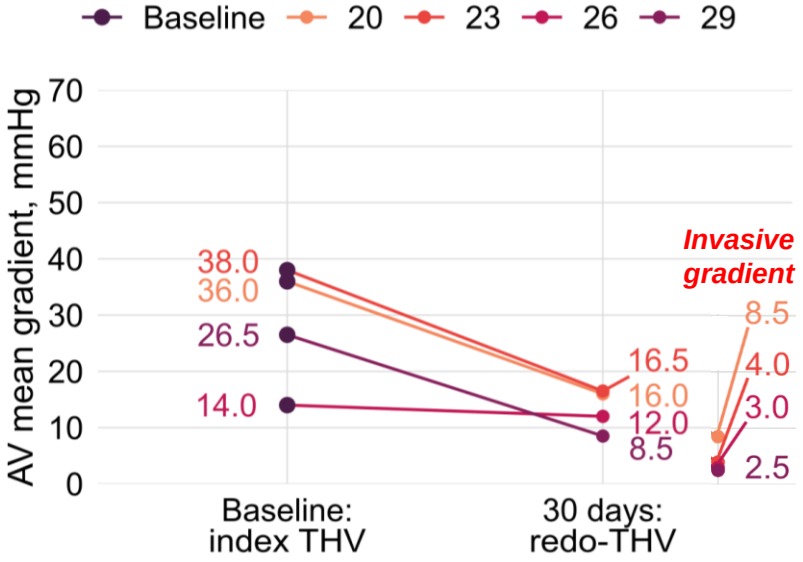
Moderate/severe intraprosthetic AR 0%
Moderate/severe PVL 0.9%

Results #7 : THV Performance (invasive)

Stratified by index THV failure mechanism



Stratified by Redo-THV size



Moderate/severe intraprosthetic AR 0%
Moderate/severe PVL 0.9%

Limitations & Mitigations

- *No control group:* ***Limits comparison with alternative reintervention strategies.***
  → Prospective design with corelab imaging and independent event adjudication reduces registry bias.

- *Single THV platform* ***(SAPIEN): Prevents comparison with other THV systems.***
  → At the time of study design, SAPIEN was the only CE-marked option.
  Its short-frame design is mostly preferred after tall-frame THV degeneration (70% of our cases).

Conclusions

Redo-TAVR ***with the balloon-expandable*** *SAPIEN THV* ***platform showed*** *high procedural success* ***with*** *low 30-day mortality* ***and*** *stroke* ***rate.***

Coronary protection ***and*** *chimney stenting* ***were frequent (15-30%), especially after tall-frame THV failure (even in larger aortic anatomies).***

These findings support redo-TAVR with SAPIEN as a *safe, effective, Heart-Team–guided reintervention* ***and provide a*** *benchmark for future studies* ***on lifetime management of aortic stenosis.***

Long-term follow-up (ongoing) ***will clarify*** *durability* ***and inform*** *future strategies****.***