Balloon-Expandable versus Self-Expanding TAVR:

a Propensity-Matched Comparison from the France-TAVI Registry

Eric Van Belle, MD, PhD on behalf of France TAVI investigators

From CHU Lille, Université de Lille, INSERM; France,

Late-Breaking clinical trial scientific sessions; AHA 2019, Philadelphia,

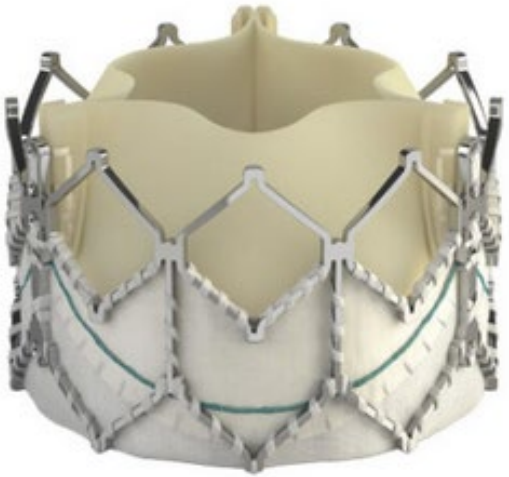
Background

- Most transcatheter heart valves (THV) available are designed on either a balloon-expandable (BE) or a self-expanding (SE) concept
- Despite major differences, both designs are recommended to be used indifferently in most of the clinical situations
- To date, no randomized study powered to compare BE-THV to SE-THV on individual endpoints has been conducted

Purpose of the study

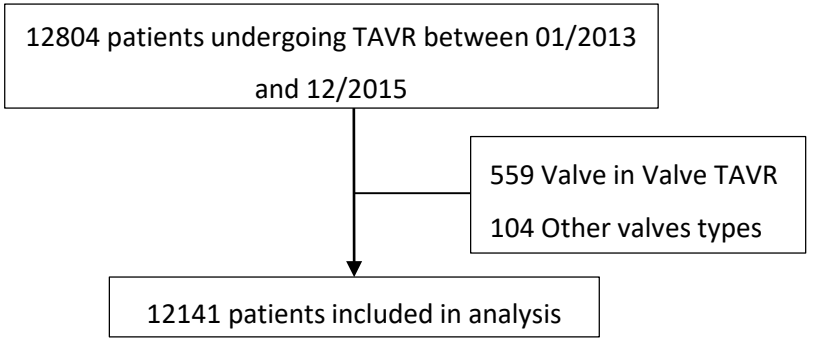
- To evaluate the impact of THV design (SE vs BE) on the risk of ParaValvular Regurgitation, intra-hospital mortality, and 2-year mortality using a nationwide propensity score matching analysis.

VS



Patient selection

- Since Jan 2013, all patients that undergone TAVR in 48/50 TAVR centers in France and gave consent were prospectively included in the FRANCE-TAVI registry (NCT01777828)
- For the purposes of the present analysis, a database containing all patients (n=12,804) included until December 31st 2015 was locked.
- Exclusion criteria :
  - Patients referred for a valve-in-valve procedures (n=559)
  - Patients treated with a different THV-design (n=104)
- The decision to perform TAVR, choices of vascular access and THV-design were based on heart-team assessment at each center.
- Both commercially available valves were used: the BE-THV SAPIEN-XT (Jan. 2013-last quarter 2014) or BE-THV SAPIEN 3 (last quarter 2014-Dec. 2015) valves (Edwards Lifesciences) and the SE-THV Corevalve family (Medtronic)



Endpoints

- 1st co primary endpoint = PVR at discharge or all-cause in-hospital mortality
- 2nd co-primary endpoint = 2-year all-cause mortality

- Secondary endpoints：
    1) each individual component of the 1st co-primary endpoint
    2) procedural and in-hospital events (requirement for a second THV, stroke, myocardial infarction, major or life-threatening bleeding, major vascular complication, permanent pacemaker)
    3) post-procedural transprosthetic gradient by echocardiography

Collection of Data and Follow-up

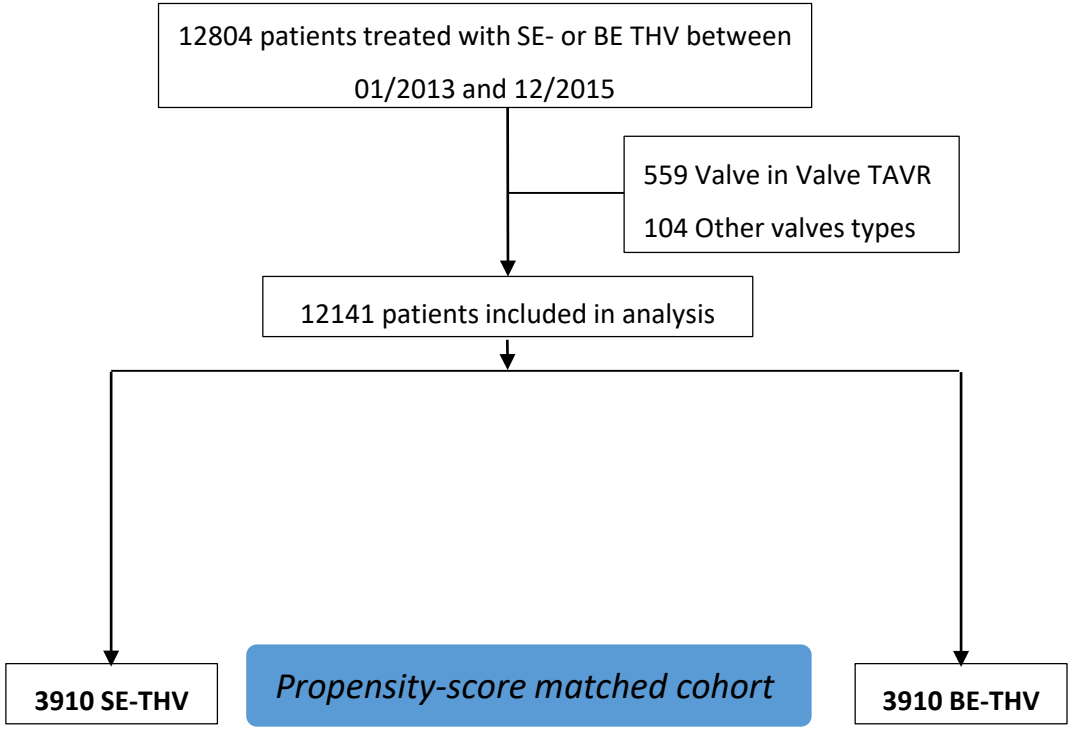
- **Mortality data were acquired in all patients from an INSEE (Institut national de la statistique et des études économiques) query on April 12th 2016,** with dates of death available and with a median follow-up of 20 months (IQR=14-30).
- Deaths were classified as cardiovascular unless a clear non-cardiovascular cause was identified.

- **Post-procedural TTE was performed before hospital discharge with a median of 3 days (IQR=2-4).**
- **AR grading was defined as "mild", "moderate" or "severe" as previously used in the France 2 registry,** according to the European and American Society of Echocardiography guidelines and Valve Academic Research Consortium(VARC)-2 recommendations.
- In-hospital complications were assessed according to the VARC-2 classification.
- AR grading and in-hospital complications were site reported and not centrally adjudicated.

Statistical analysis and study flow chart

Main analysis: Propensity score matched cohorts:

- Prop. Score: 25 clinical, anatomical, and procedural variables
- Time of the procedure (within 3 months of each other)
- Adjusted on each center
- Missing data were handeld by multiple imputations (m=10).



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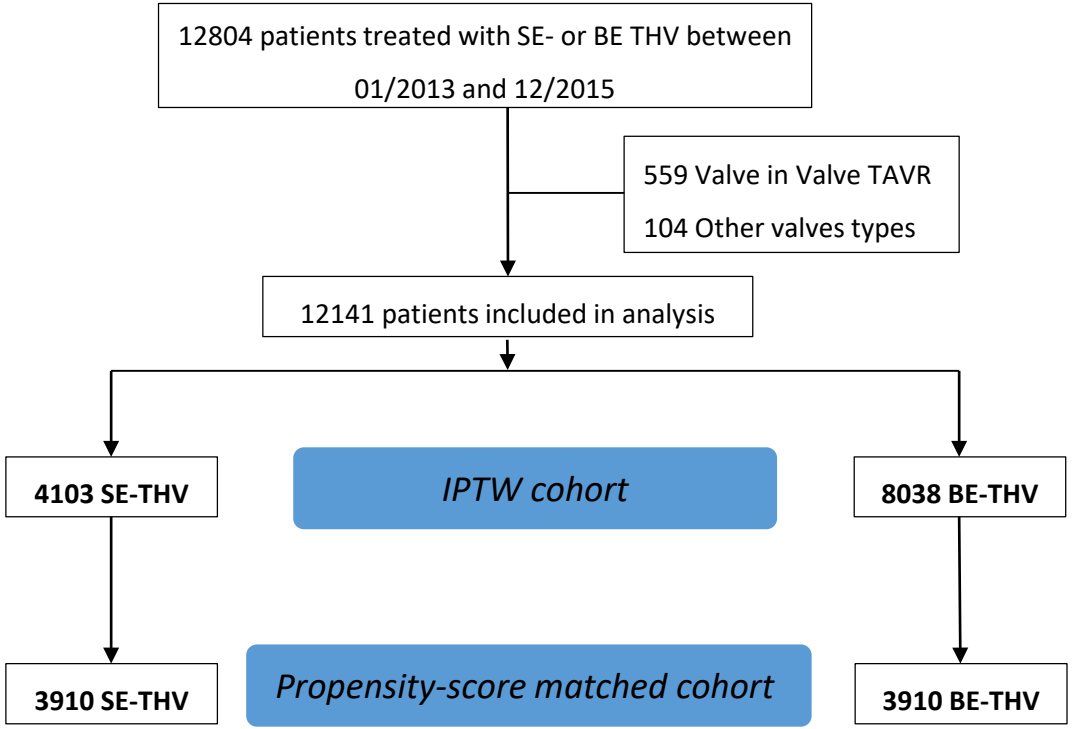
Sensitivity analysis: IPTW cohort analysis

- Propensity score was used to weight each subject by the inverse probability of treatment (stabilized inverse propensity score as weight) and generate an **inverse probability treatment weighting** (IPTW) cohort.



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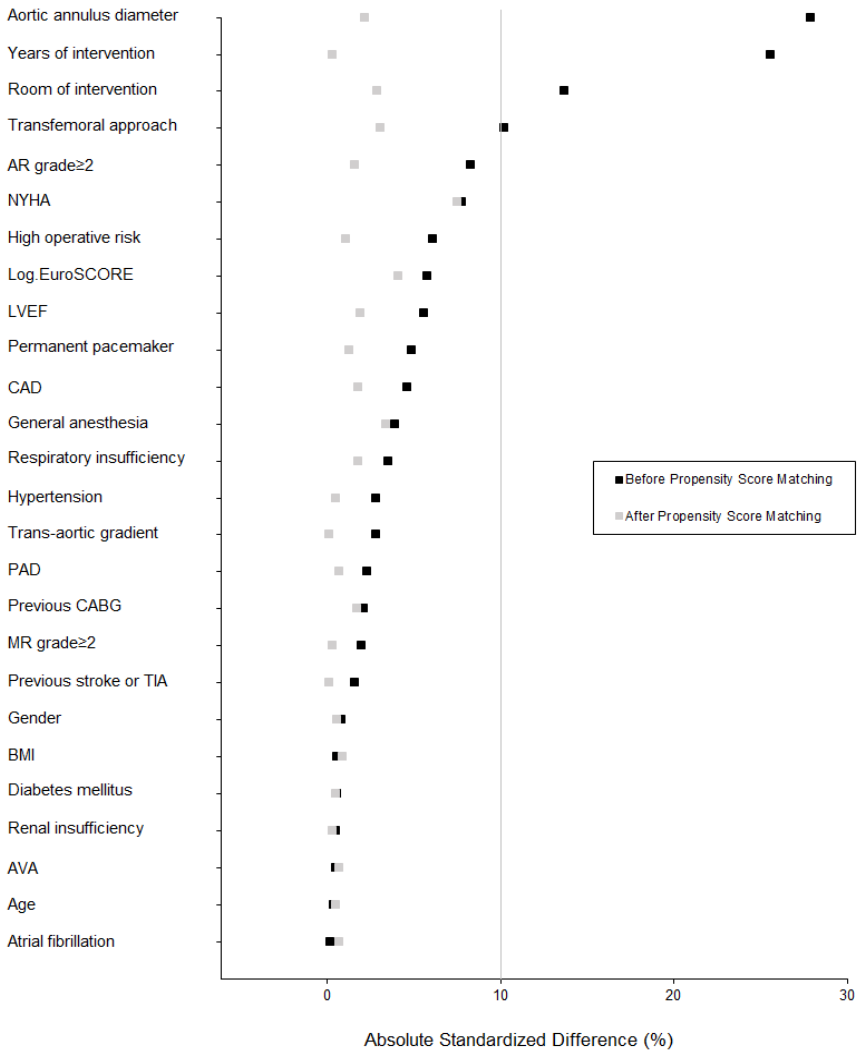
RESULTS

Baseline patients characteristics

	Before matching	
Characteristics	**SE-THV (n=4103)**	**BE-THV (n=8038)**
Age	83.5 ± 7.0	83.5 ± 7.1
Men	2027 (49.4)	3939 (49.0)
Euroscore	14.0 (9.0 to 22.5)	15.0 (9.6 to 23.0)
NYHA 3	2257 (55.0)	4698 (58.4)
CAD	1830 (44.6)	3401 (42.3)
PAD	965 (23.5)	1814 (22.6)
Renal insufficiency	210 (5.1)	421 (5.2)
LVEF	54.7 ± 13.7	55.5 ± 13.7
Aortic annulus diameter	24.2 ± 2.8	23.5 ± 2.7
Transfemoral approach	3287 (80.1)	6754 (84.0)
Years of intervention		
-01/2013 to 12/2014	2619 (63.8)	4123 (51.3)
-01/2015 to 12/2015	1484 (36.2)	3915 (48.7)



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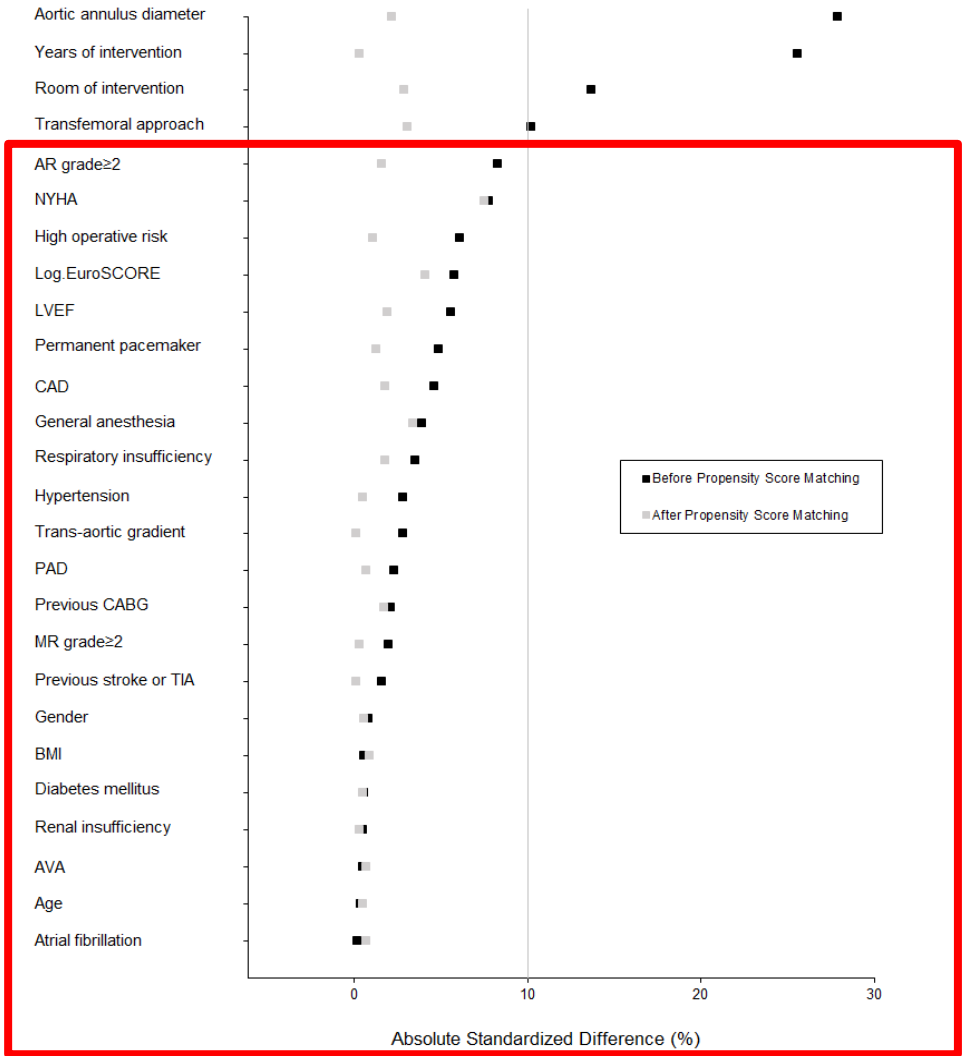

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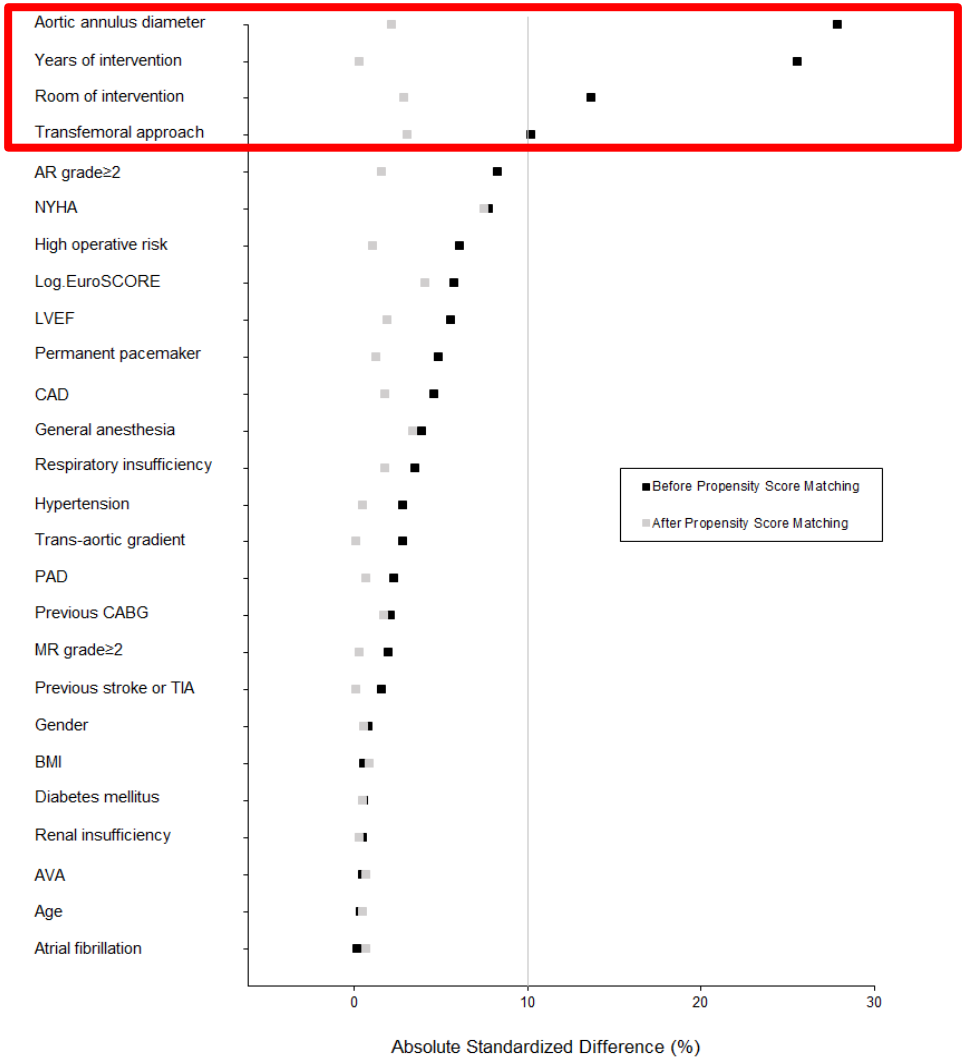

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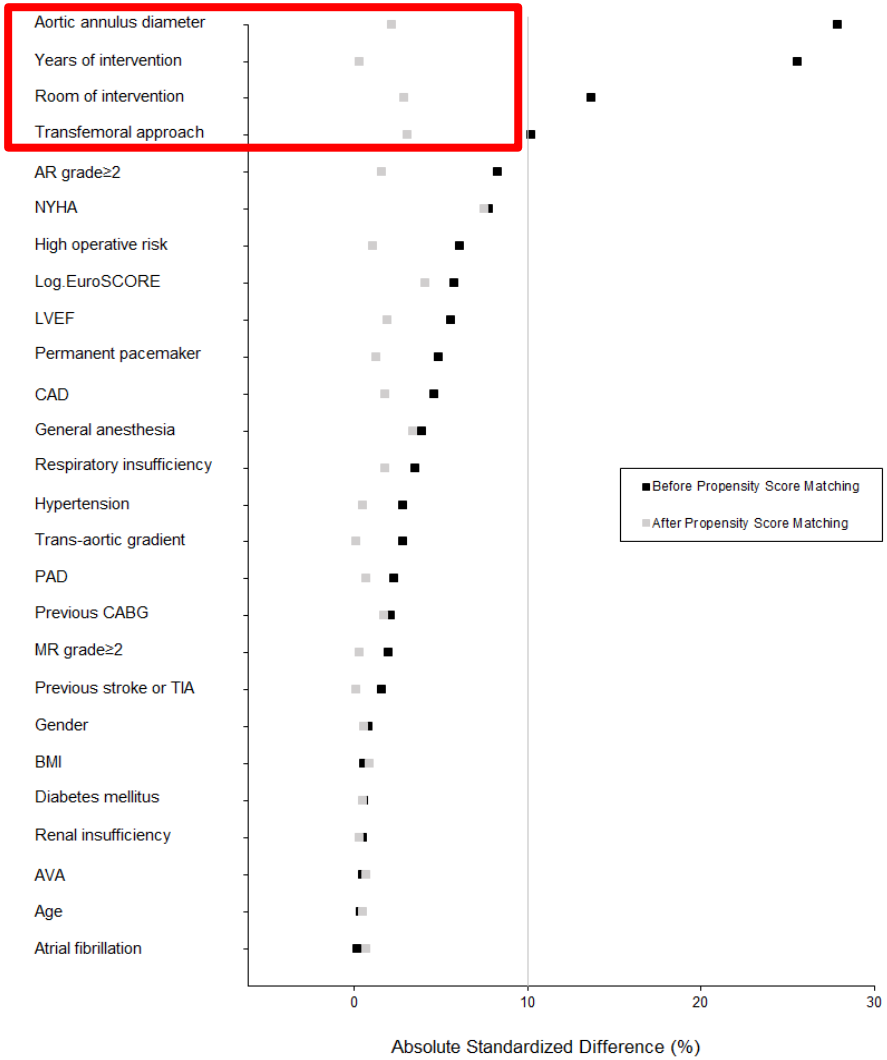
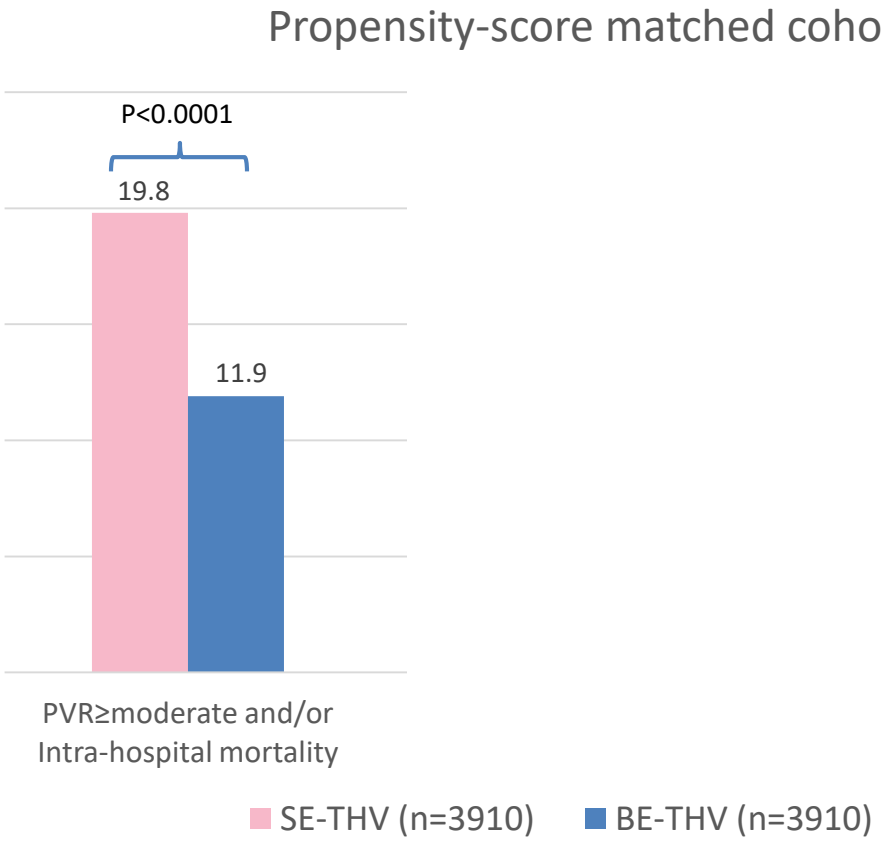


1st co-primary outcome : PVR≥moderate or all-cause in-hospital mortality



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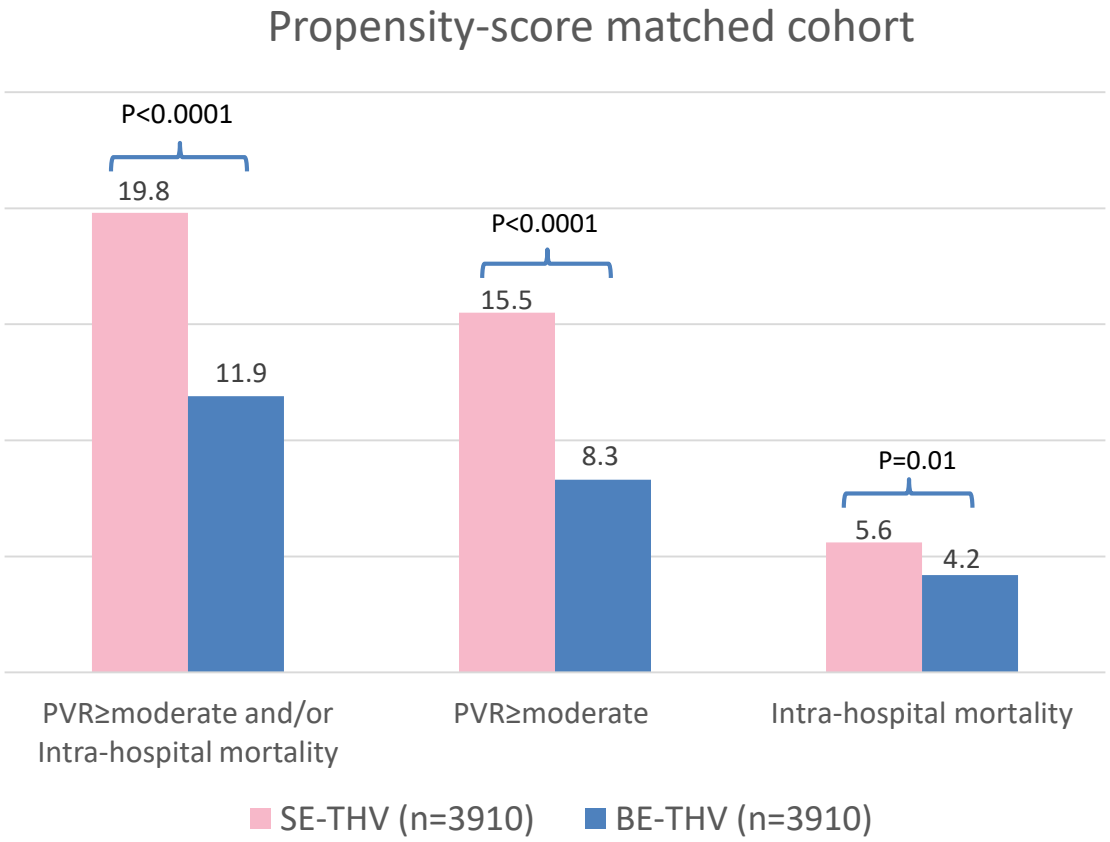

Procedural and in-hospital events

Propensity-score matched cohort				
	SE-THV (n=3910)	**BE-THV (n=3910)**	Effect size (95%CI)	P-value
Second THV	143 (3.7)	38 (1.0)	3.79 (2.40 to 5.99)†	<0.0001
Stroke	96 (2.5)	70 (1.8)	1.38 (0.98 to 1.94)†	0.058
Myocardial infarction	14 (0.4)	7 (0.2)	2.07 (1.11 to 3.88)†	0.02
Major or life-threatening bleeding‡	398 (10.2)	356 (9.1)	1.03 (0.89 to 1.19)†	0.68
Major vascular complication	292 (7.5)	270 (6.9)	1.02 (0.85 to 1.22)†	0.81
Permanent pacemaker implantation	871 (22.3)	431 (11.0)	2.08 (1.83 to 2.35)†	<0.0001
Mean gradient (median, IQR)	7 (5 to 10)	10 (7 o 13)	-0.21 (-0.24 to -0.19)‖	<0.0001
Mean gradient>20 mmHg	75 (1.9)	102 (2.6)	0.75 (0.48 to 1.16)‖	0.17

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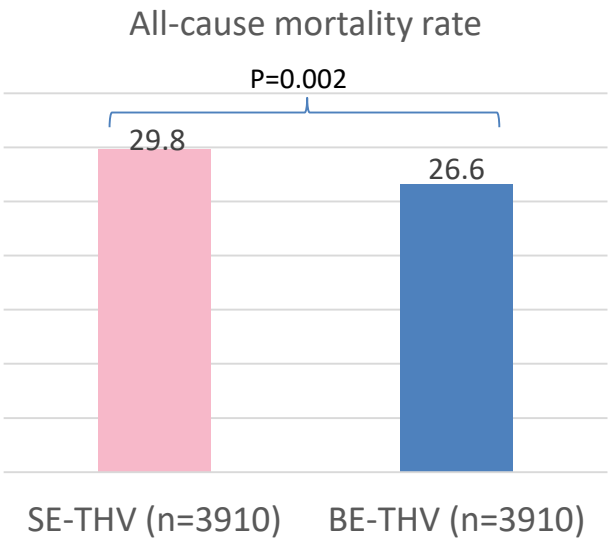
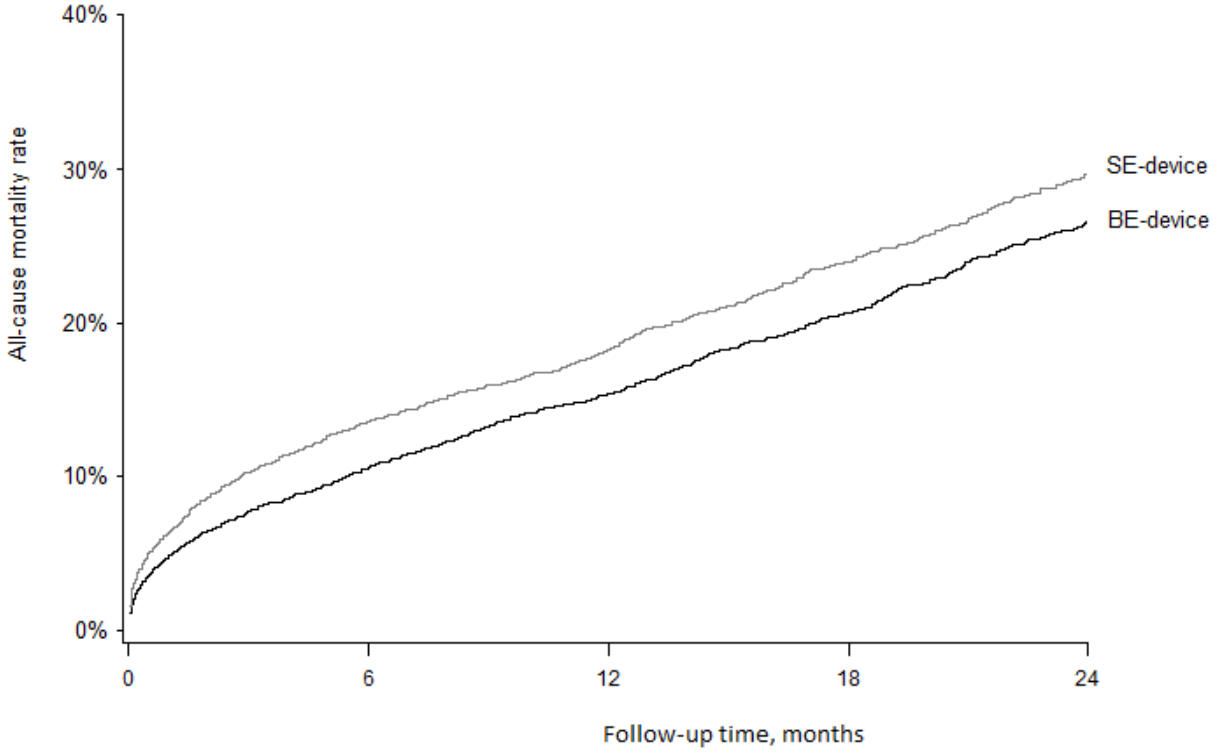
2nd co-Primary outcome : 2 year all-cause mortality in PS-matched cohort





Number of patients at risk :

SE-device	3910	2704	2077	1333	859
BE-device	3910	2843	2156	1405	888

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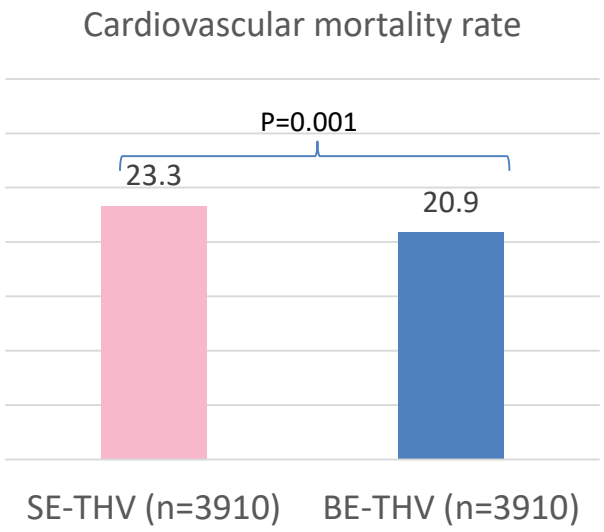

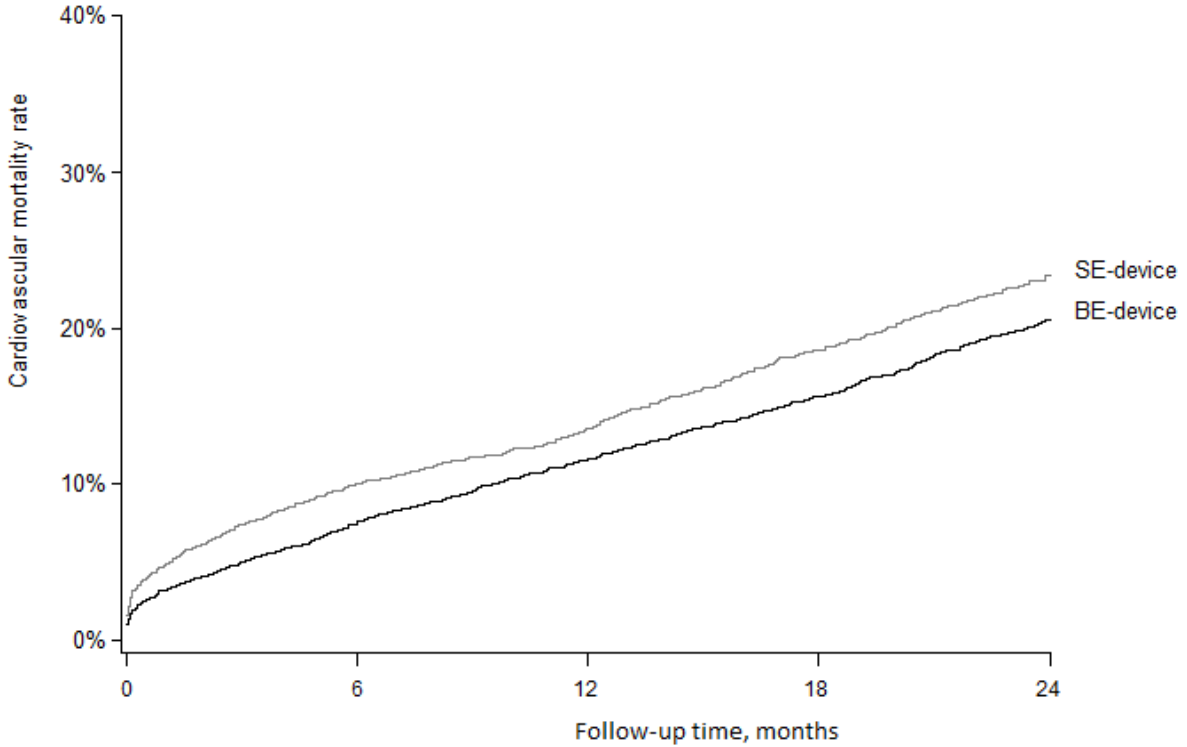

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2nd co-Primary outcome : Effect of time on all-cause mortality

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Outcomes	**SE-THV (n=3910)**	**BE-THV (n=3910)**	Effect size (95%CI)	P-value
Follow-up all-cause mortality	899 (29.8)	801 (26.6)	1.17 (1.06 to 1.28)*	0.002
• ***0 to 3 months***	381	286	1.37 (1.16 to 1.60)*	0.0001
• ***3 to 6 months***	104	92	1.23 (0.88 to 1.70)*	0.22
• ***6 month to end of follow-up***	414	423	1.00 (0.85 to 1.18)*	0.89

Values in brackets in columns 2 and 3 are cumulative incidence at 2-year expresses as % (calculated using Kalbfleisch and Prentice for follow-up hospitalizations by treating death as competing risk, or using Kaplan-Meier method for mortality) * calculated using a Fine and Gray or Cox's regression model stratified by center with the robust sandwich variance estimate to account the matched sets.

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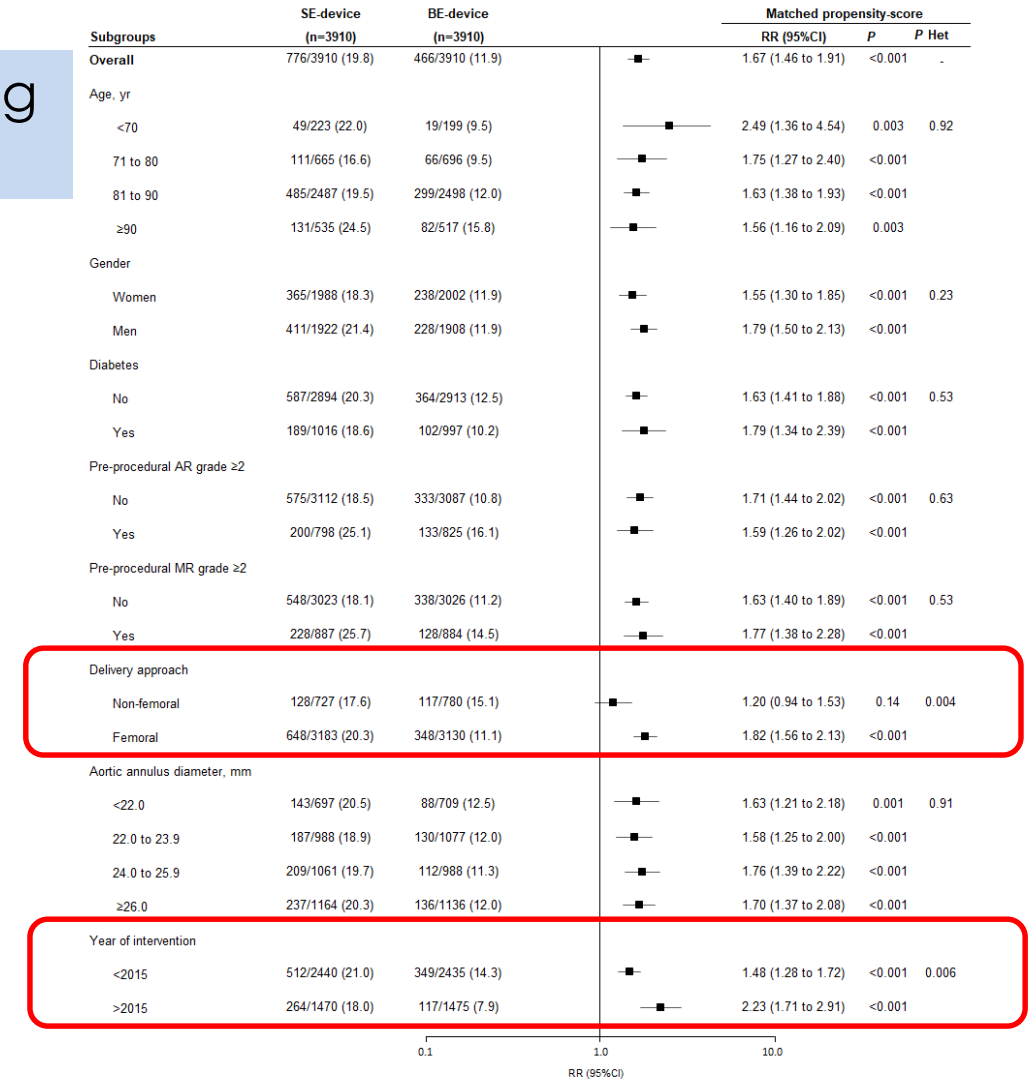
1st co-primary outcome according to key subgroups

The relation between the occurrence of outcome and THV-design was consistent across key subgroups, except for delivery approach and year of intervention:

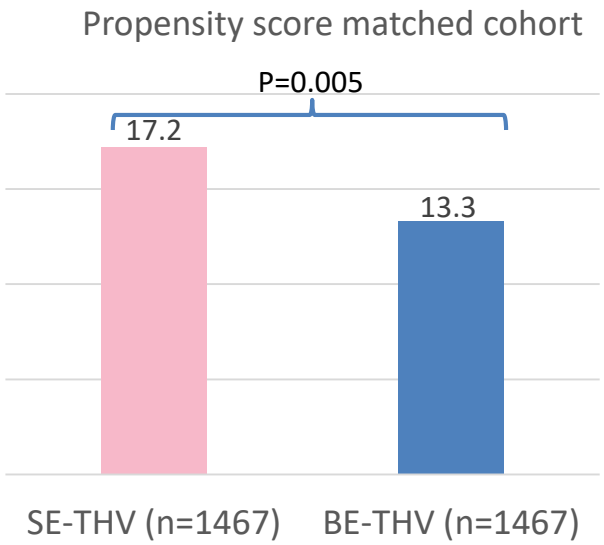
The difference was stronger in femoral TAVR (RR=1.82; 95%CI:1.56-2.13) than in non-femoral TAVR (RR=1.20; 95%CI:0.94-1.53, p for heterogeneity=0.004)

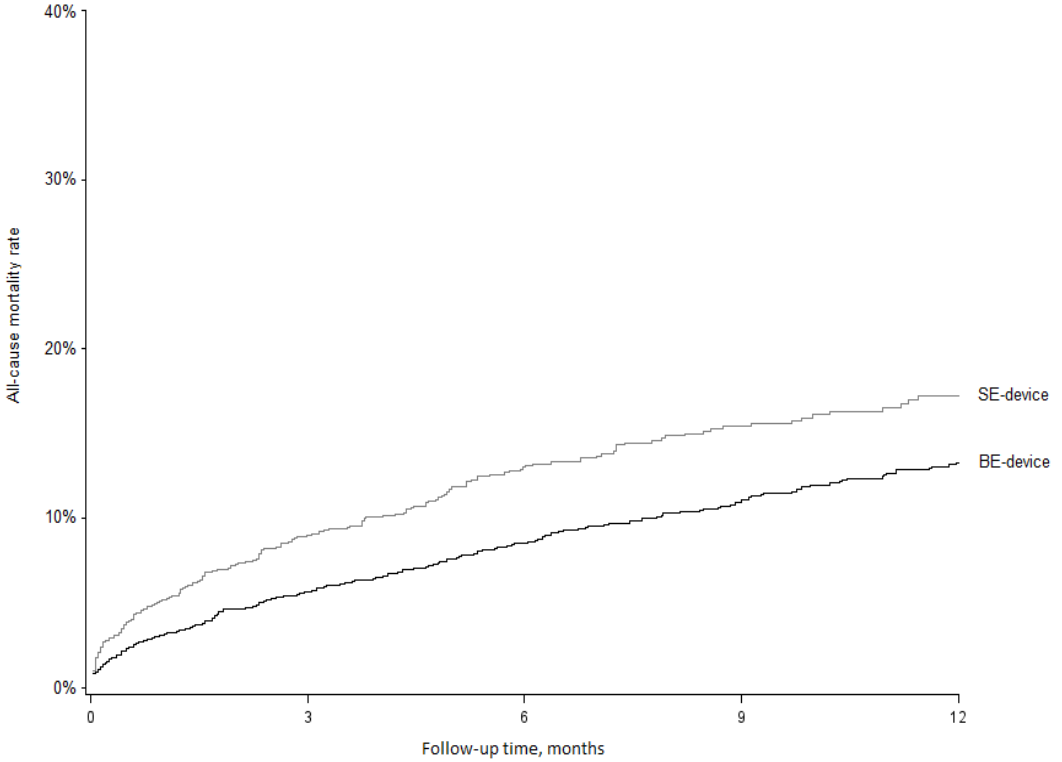
The difference was also stronger in the second (≥01 January 2015, RR=2.23; 95%CI:1.71-2·94) as compared to the first-study period (<01 January 2015, RR=1.48; 95%CI:1.28-1.72; p for heterogeneity=0.006)



Subgroups	SE-device (n=3910)	BE-device (n=3910)	Matched propensity-score RR (95%CI)	*P*	*P* Het
Overall	776/3910 (19.8)	466/3910 (11.9)	1.67 (1.46 to 1.91)	<0.001	-
Age, yr					
<70	49/223 (22.0)	19/199 (9.5)	2.49 (1.36 to 4.54)	0.003	0.92
71 to 80	111/665 (16.6)	66/696 (9.5)	1.75 (1.27 to 2.40)	<0.001	
81 to 90	485/2487 (19.5)	299/2498 (12.0)	1.63 (1.38 to 1.93)	<0.001	
≥90	131/535 (24.5)	82/517 (15.8)	1.56 (1.16 to 2.09)	0.003	
Gender					
Women	365/1988 (18.3)	238/2002 (11.9)	1.55 (1.30 to 1.85)	<0.001	0.23
Men	411/1922 (21.4)	228/1908 (11.9)	1.79 (1.50 to 2.13)	<0.001	
Diabetes					
No	587/2894 (20.3)	364/2913 (12.5)	1.63 (1.41 to 1.88)	<0.001	0.53
Yes	189/1016 (18.6)	102/997 (10.2)	1.79 (1.34 to 2.39)	<0.001	
Pre-procedural AR grade ≥2					
No	575/3112 (18.5)	333/3087 (10.8)	1.71 (1.44 to 2.02)	<0.001	0.63
Yes	200/798 (25.1)	133/825 (16.1)	1.59 (1.26 to 2.02)	<0.001	
Pre-procedural MR grade ≥2					
No	548/3023 (18.1)	338/3026 (11.2)	1.63 (1.40 to 1.89)	<0.001	0.53
Yes	228/887 (25.7)	128/884 (14.5)	1.77 (1.38 to 2.28)	<0.001	
Delivery approach					
Non-femoral	128/727 (17.6)	117/780 (15.1)	1.20 (0.94 to 1.53)	0.14	0.004
Femoral	648/3183 (20.3)	348/3130 (11.1)	1.82 (1.56 to 2.13)	<0.001	
Aortic annulus diameter, mm					
<22.0	143/697 (20.5)	88/709 (12.5)	1.63 (1.21 to 2.18)	0.001	0.91
22.0 to 23.9	187/988 (18.9)	130/1077 (12.0)	1.58 (1.25 to 2.00)	<0.001	
24.0 to 25.9	209/1061 (19.7)	112/988 (11.3)	1.76 (1.39 to 2.22)	<0.001	
≥26.0	237/1164 (20.3)	136/1136 (12.0)	1.70 (1.37 to 2.08)	<0.001	
Year of intervention					
<2015	512/2440 (21.0)	349/2435 (14.3)	1.48 (1.28 to 1.72)	<0.001	0.006
>2015	264/1470 (18.0)	117/1475 (7.9)	2.23 (1.71 to 2.91)	<0.001	

2nd co-Primary outcome: all-cause mortality (sensitivity analysis of patients treated after 01/2015)





Number of patients at risk :

SE-device	1466	1018	752	568	306
BE-device	1466	1094	837	598	326

Multivariable analysis – Predictors of all-cause mortality

	HR (95% CI)	P-value
Paravalvular Regurgitation		
None	1.00 (reference)	-
Mild	1.13 (1.01-1.27)	0.032
Moderate	1.42 (1.19-1·68)	<0·001
Severe	1.86 (1.19-2.90)	0·006
THV design (BE-THV as reference)		
0-3 months	1.42 (1.17-1·63)	<0.001
3-6 months	1.20 (0.98-1.61)	0.23
6 month-end of follow-up	0.94 (0.77-1.06)	0.41

HRs were calculated using Backward-stepwise multivariable Cox's regression after handling missing values by multiple imputation procedure (m=10); candidate factors were factors associated with mortality imodels n univariable Cox's regression models (at p<0·10):**Age ≥90-years, Men, NYHA, Euroscore, High operative risk, BMI, Diabetes, hypertension, CAD, previous stroke/TIA, PAD, Atrial fibrillation, permanent pacemaker, respiratory insuffisiency, annulus diameter, LVEF, AVA, Transaortic gradient, MR grade≥2, femoral approach, PVR, second THV, Stroke, myocardial infarction, major/life threatening bleeding, permanent pacemaker implantation**

Limitations

- This is a comparison between THV designs from an observational registry and not a randomized controlled trial
- Potential unmeasured residual confounders might remain despite the PS matching analysis
- PVR grading and clinical events (except mortality) were site-reported
- Some of the most recent THV iterations were not part of the investigation

Conclusion

- Largest study to date (n=12,141) allowing a propensity-score comparison of outcomes between SE-THV and BE-THV when used to treat patients with native aortic stenosis.

- The use of SE-THV was associated with a higher risk of PVR at discharge, a higher risk of in-hospital mortality, and a higher risk of 2 year mortality, as compared with BE-THV.

- The higher risk of mortality persisted after multivariable adjustment including PVR severity and other peri-procedural events.

- These results suggest that the two most widely used THV designs may not achieve the same clinical outcomes.

- Overall, the present study strongly supports to conduct a randomized trial powered to compare head-to-head the most recent iterations of SE- and BE-THV on all-cause mortality.

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Balloon-Expandable versus Self-Expanding Transcatheter Aortic Valve Replacement: a Propensity-Matched Comparison from the France-TAVI Registry

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