Echocardiographic Results of Transcatheter Versus Surgical Aortic Valve Replacement in Women with Severe Aortic Stenosis

The RHEIA Trial

RHEIA

Philippe Pibarot, PhD, DVM, on Behalf of the RHEIA Investigators

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Institut Universitaire de Cardiologie et de Pneumologie de Québec / Québec Heart & Lung Institute

Université LAVAL

Disclosure of Relevant Financial Relationships

Within the prior 24 months, I, Philippe Pibarot, 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 Relationshipb	**Ineligible Company**
Grant/Research Support	Edwards Life Sciences, Boston Sc., Novartis, Pi-Cardia, Cardiac Success

RHEIA Trial: ***Investigator Initiated and Sponsored Trial funded by Edwards Lifesciences.***

Background And Objectives

- In the Randomized researcH in womEn all comers wIth Aortic stenosis (RHEIA) trial, the incidence of the primary endpoint of death, stroke, or rehospitalization at 1-year was lower with transcatheter aortic valve implantation (TAVI) than with surgical aortic valve replacement (SAVR).

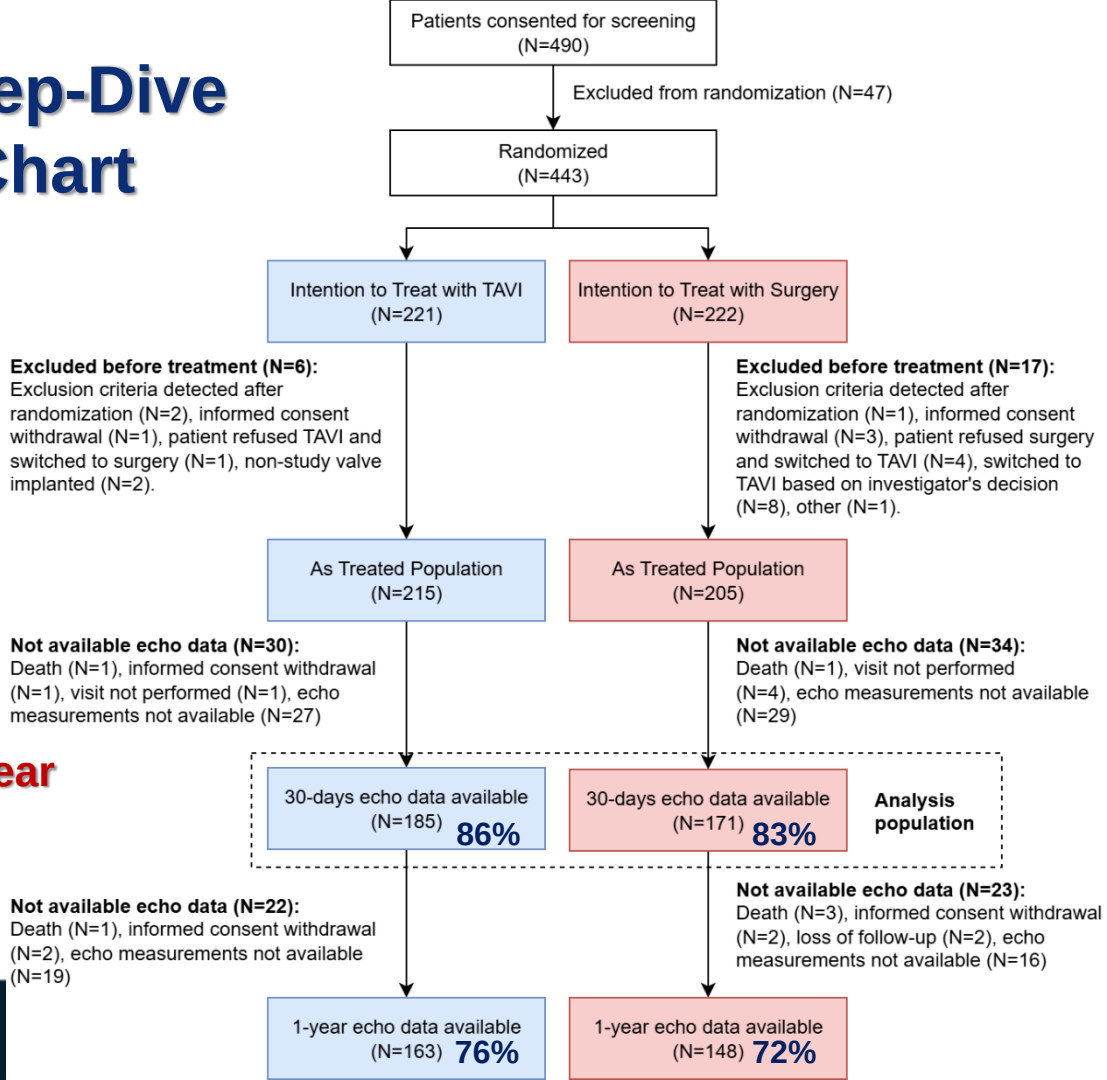
Study Objectives:

- i) To compare echocardiographic findings in women with severe AS following SAVR or TAVI.
- ii) To determine the association between echocardiographic parameters at 30-days and clinical outcomes at 1-year.

RHEIA Echo Deep-Dive Study Flow Chart

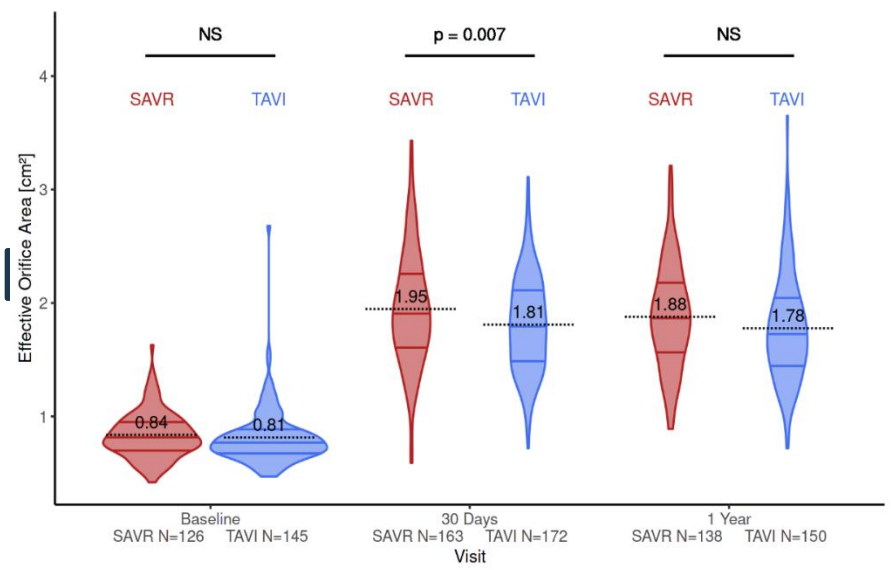
As treated population

Baseline, 30 days, and 1 Year TTEs analyzed by an echo corelab

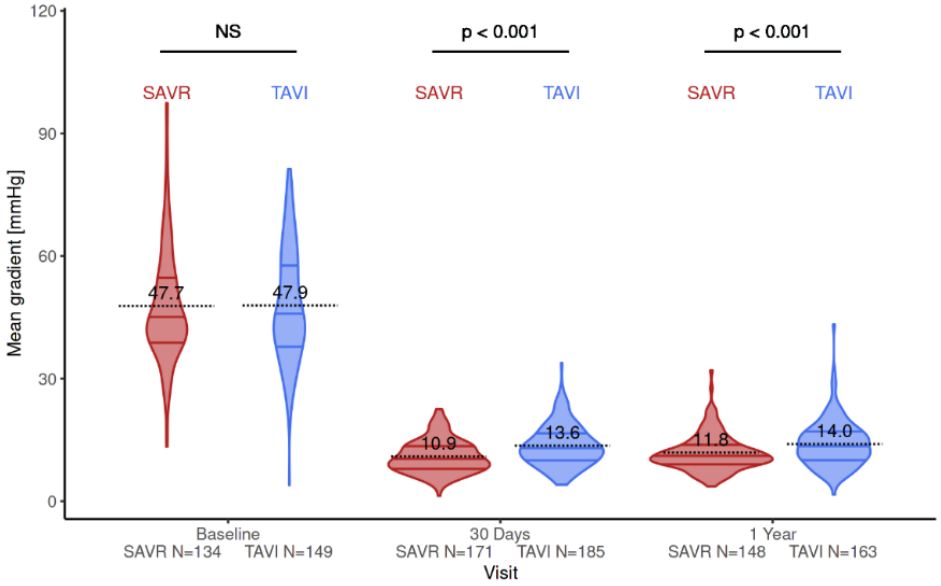


Aortic Valve Hemodynamics in TAVI vs. SAVR

Aortic Valve Area (cm^2)

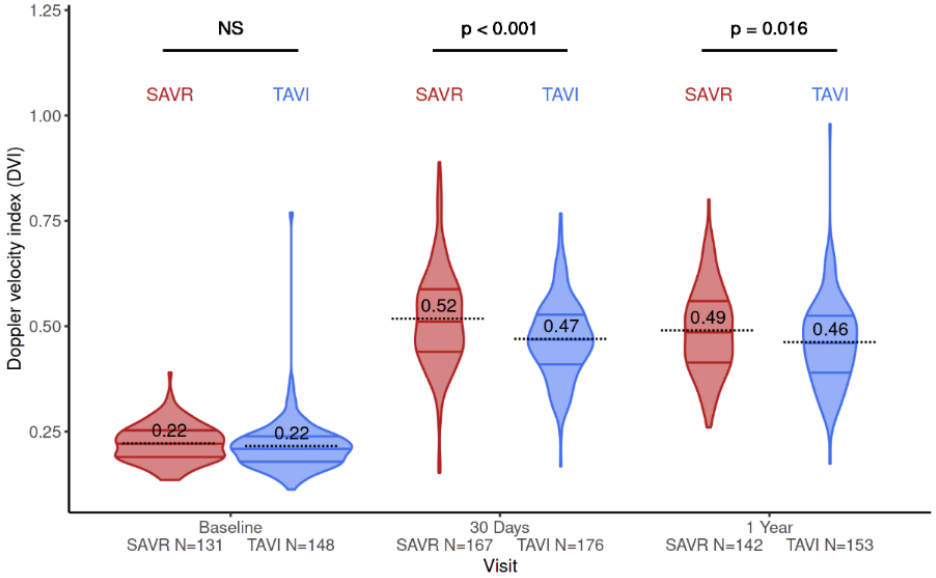


Mean Gradient (mmHg)



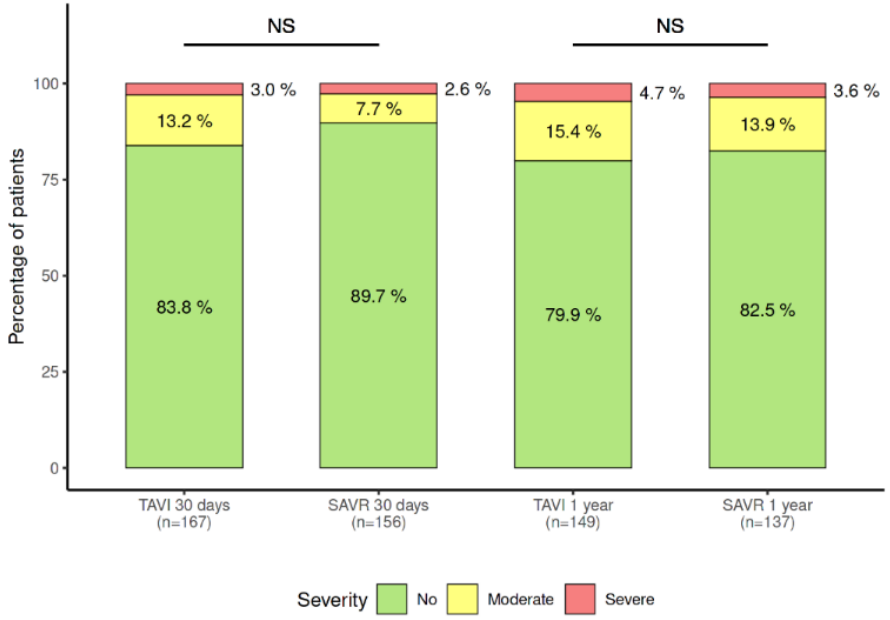
Aortic Valve Hemodynamics in TAVI vs. SAVR

Doppler Velocity Index

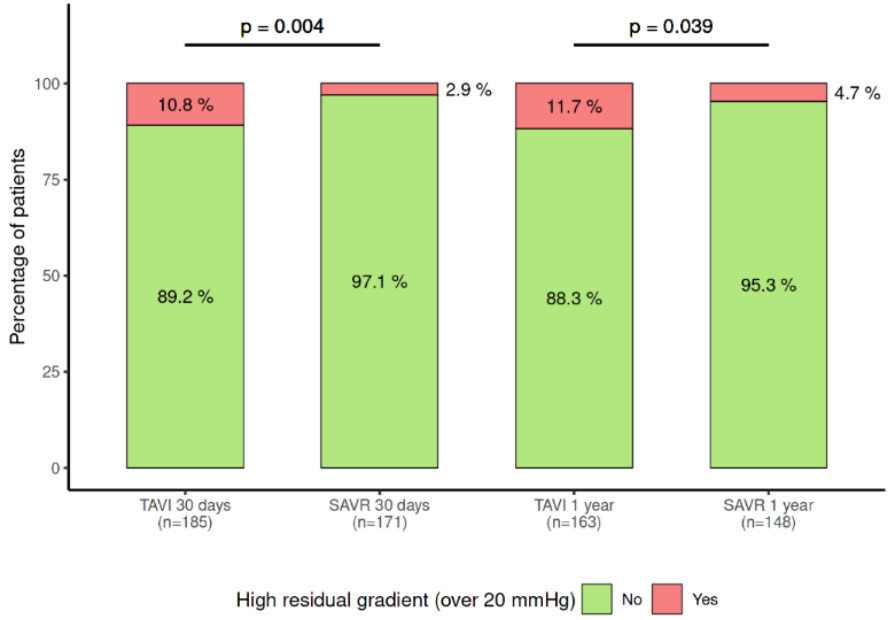


Aortic Valve Hemodynamics in TAVI vs. SAVR

Prosthesis-Patient Mismatch

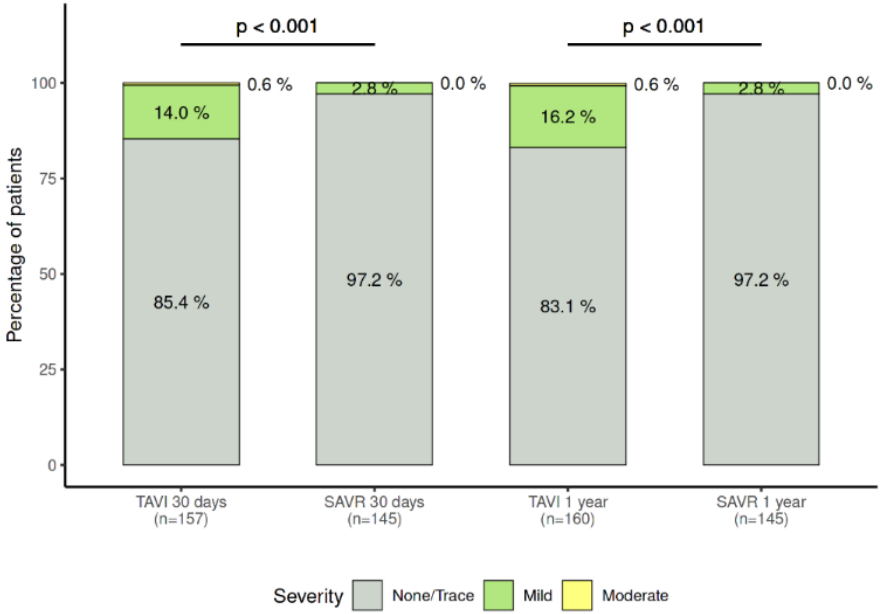


High Residual Gradient (>20 mmHg)



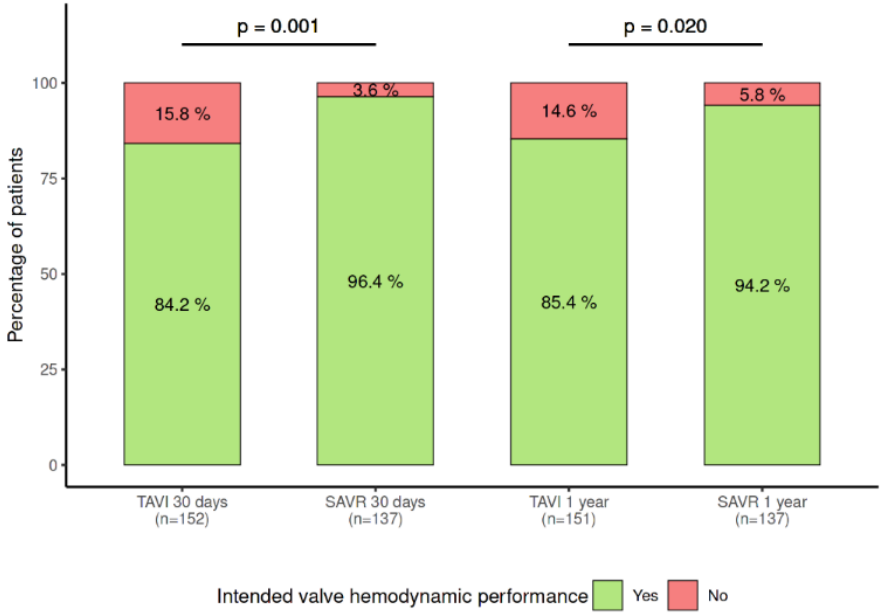
Aortic Valve Hemodynamics in TAVI vs. SAVR

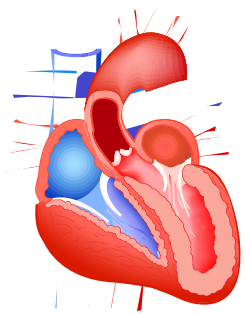
Paravalvular Aortic Regurgitation



Intended Valve Hemodynamic Performance

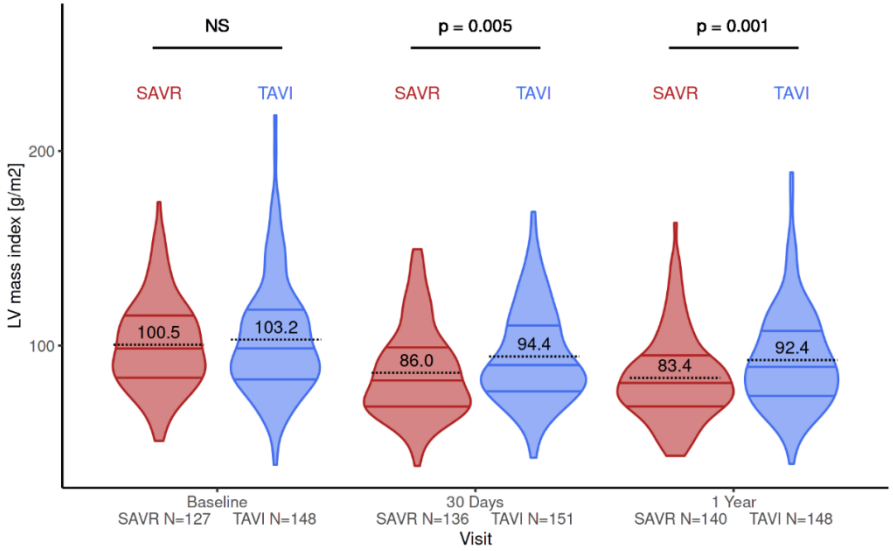
(VARC3: mean gradient <20 mmHg, DVI >0.25, and PVL <moderate)



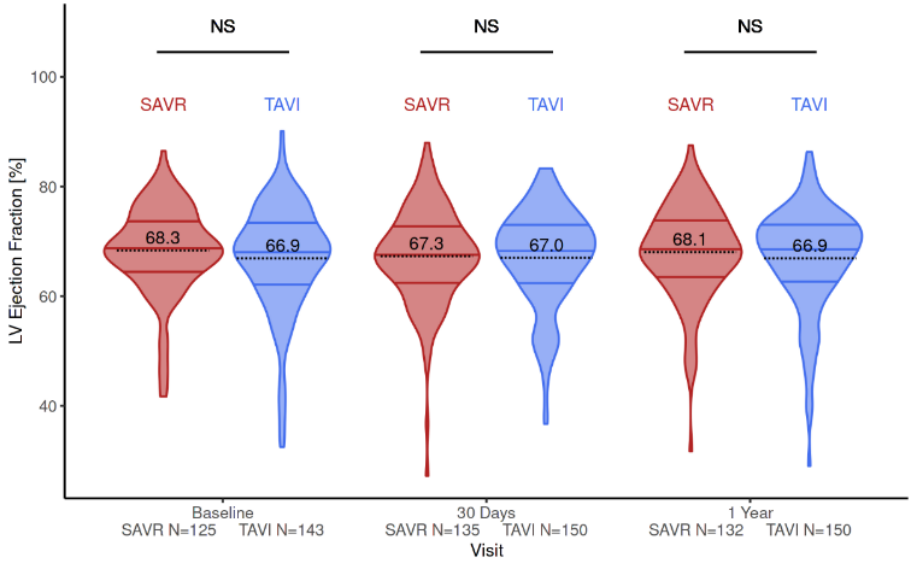


LV Remodeling and Systolic Function in TAVI vs. SAVR

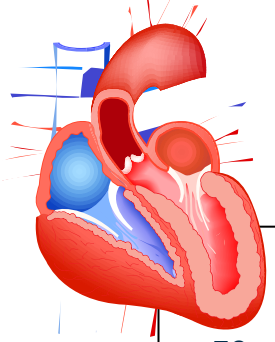
LV Mass Index (g/m²)

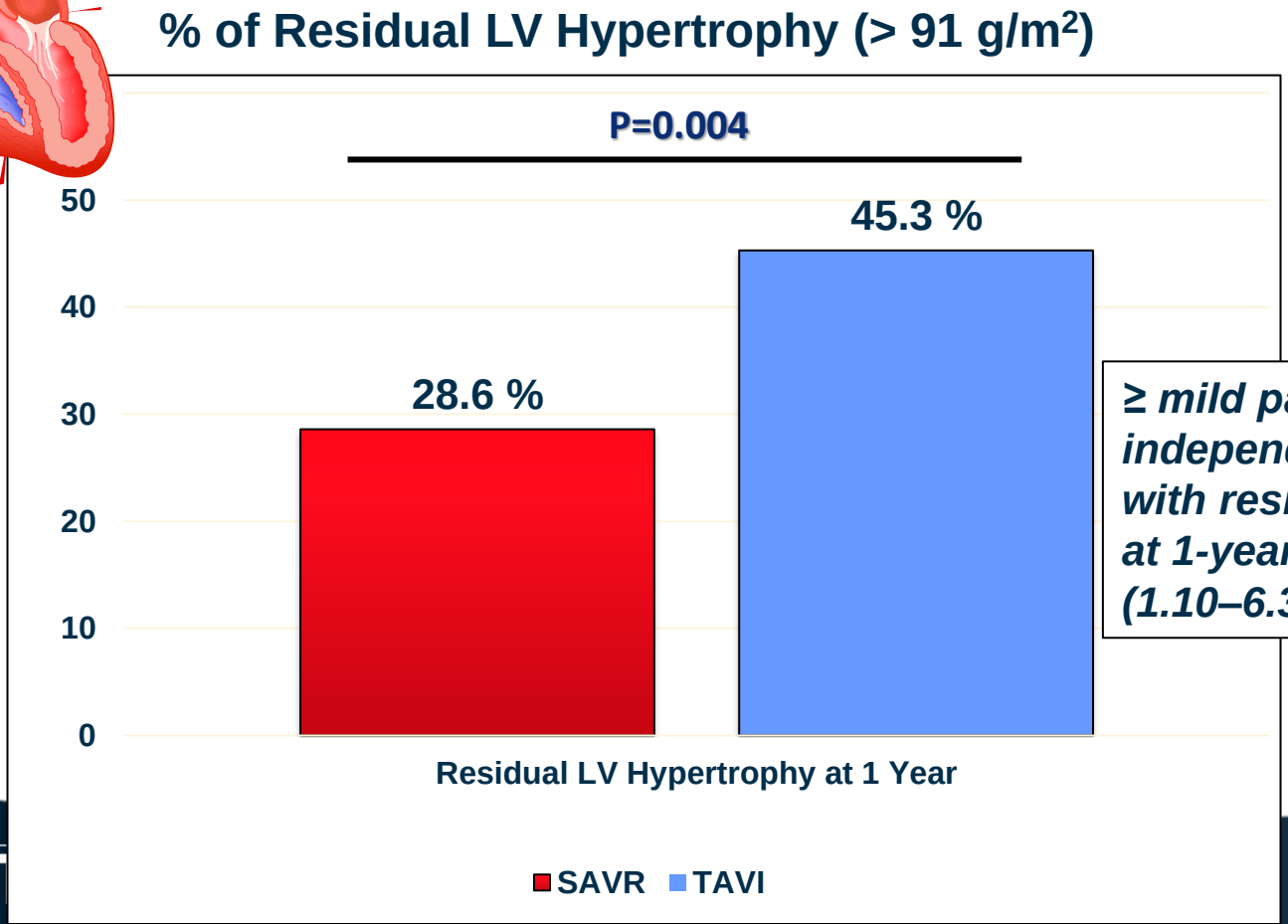


LVEF (%)

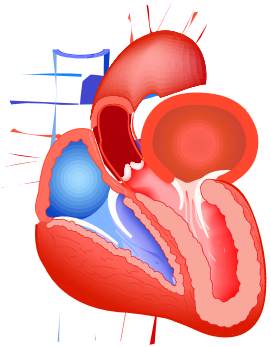


Residual LV Hypertrophy in TAVI vs. SAVR

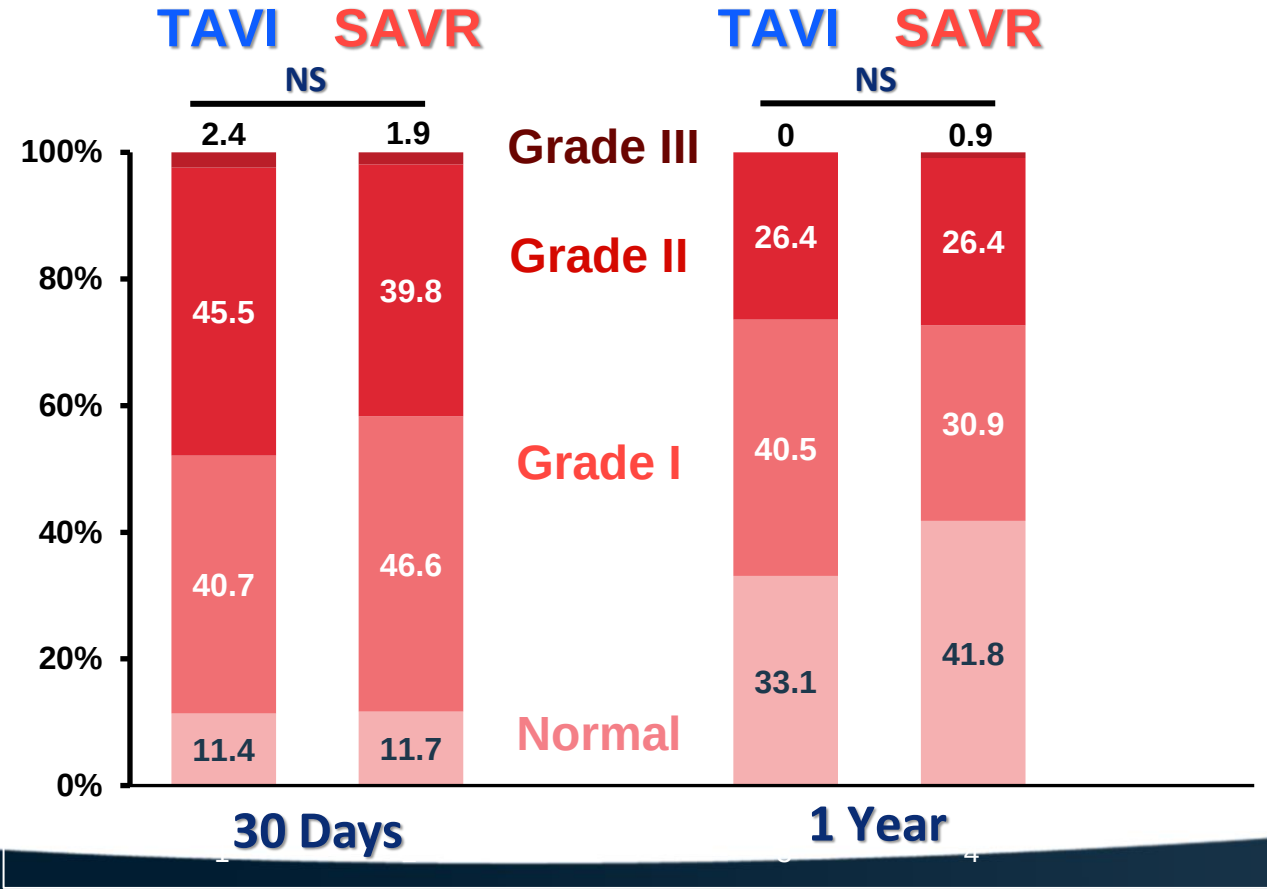


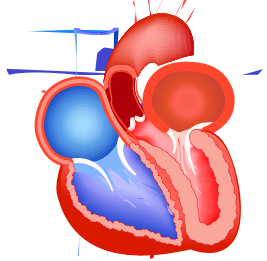


≥ mild paravalvular AR was independently associated with residual LV hypertrophy at 1-year (Odds Ratio: 2.60 (1.10–6.34); p=0.03).



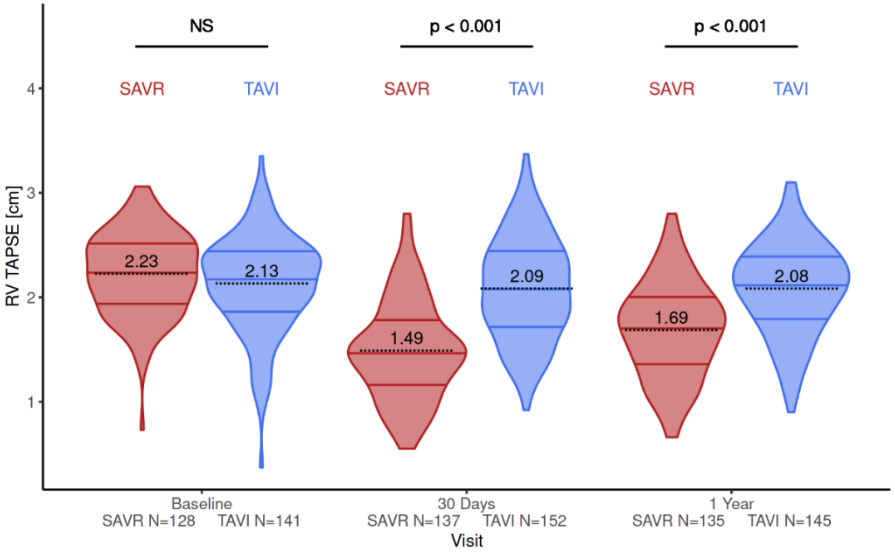
LV Diastolic Function in TAVI vs. SAVR



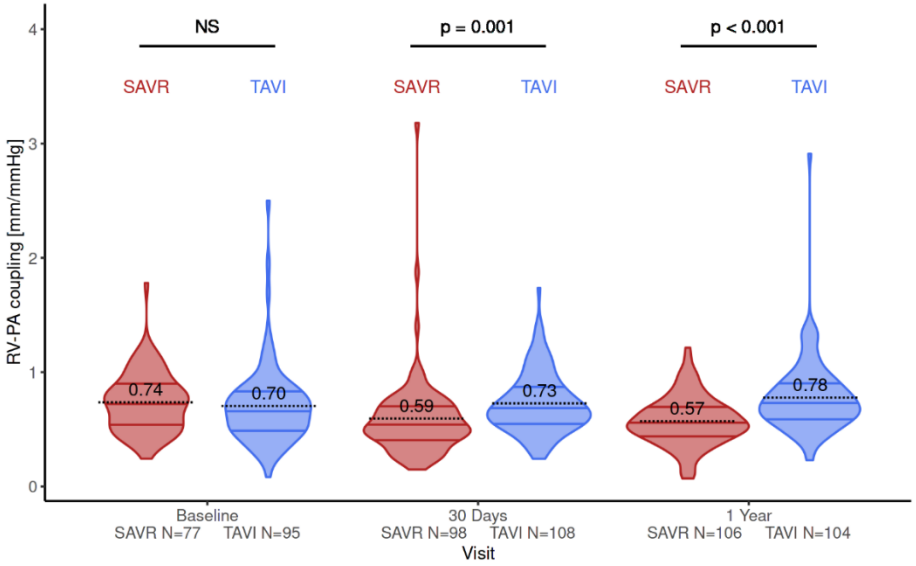


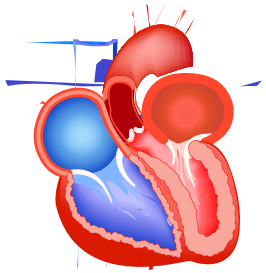
RV Systolic Function and PA Coupling in TAVI vs. SAVR

TAPSE (cm)

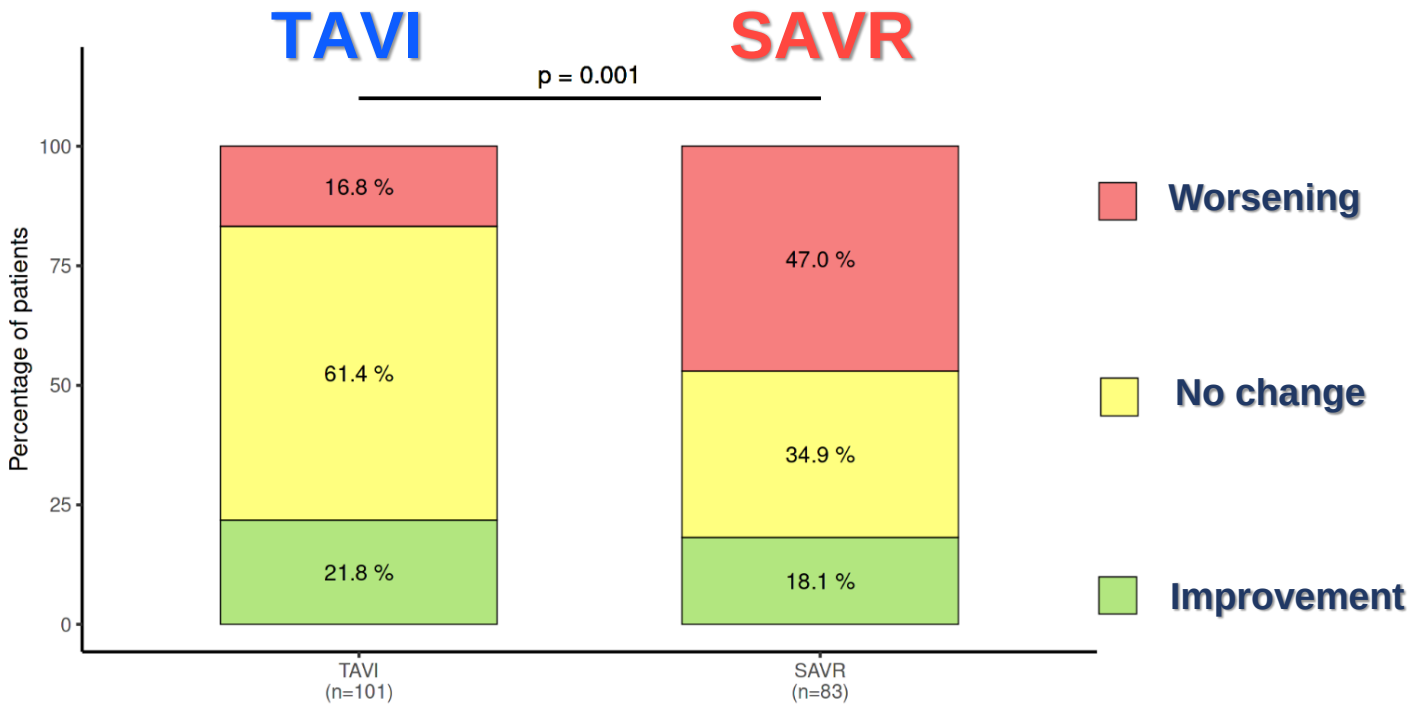


RV-PA Coupling: TAPSE / PASP (mm/mmHg)

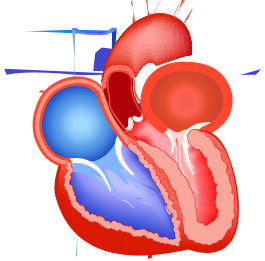




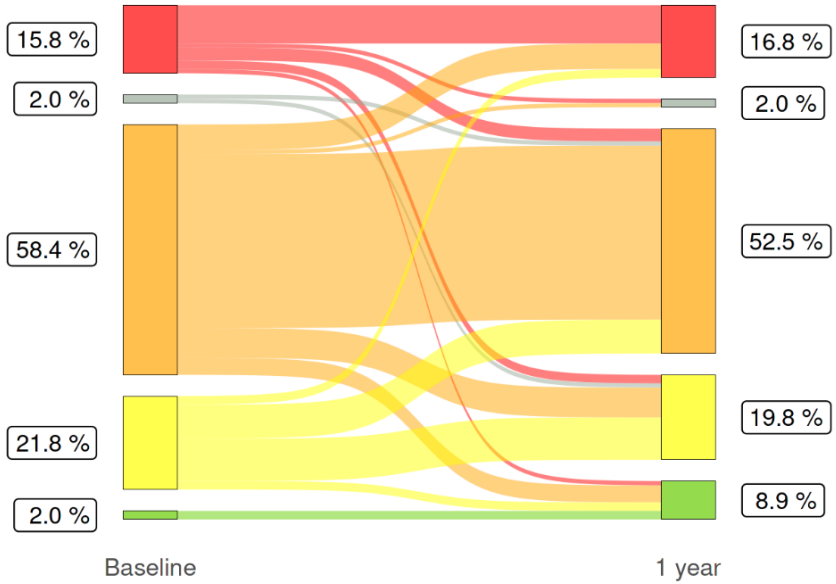
Evolution of Cardiac Damage Stage from Baseline to 1 Year in TAVI vs. SAVR



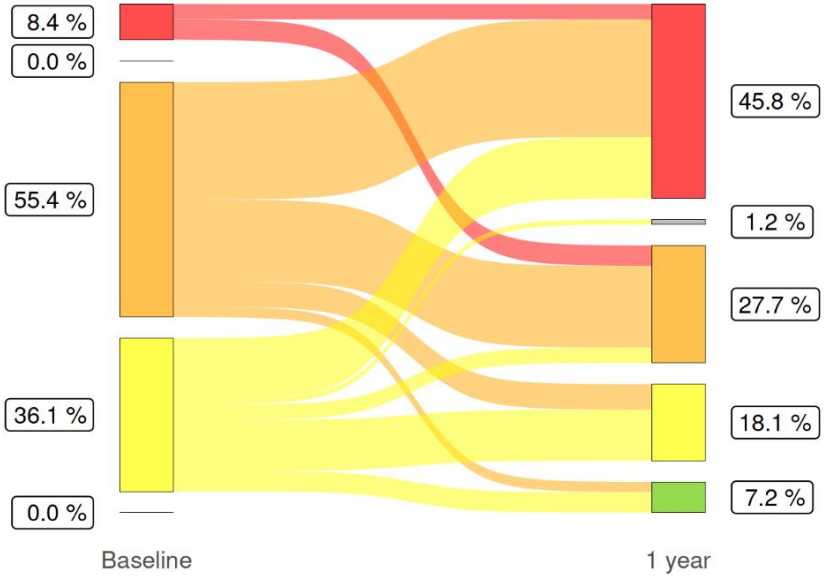
Evolution of Cardiac Damage Stage from Baseline to 1 Year in TAVI vs. SAVR



TAVI



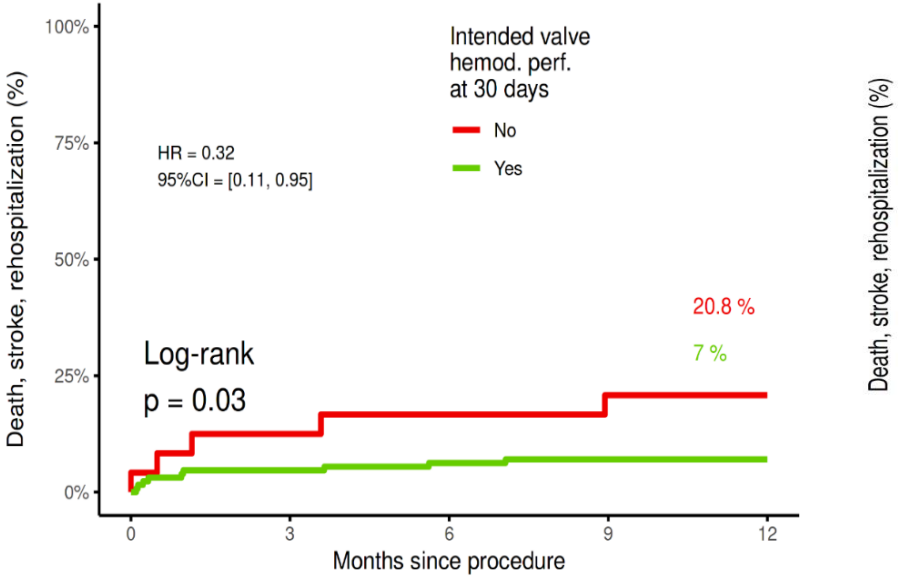
SAVR



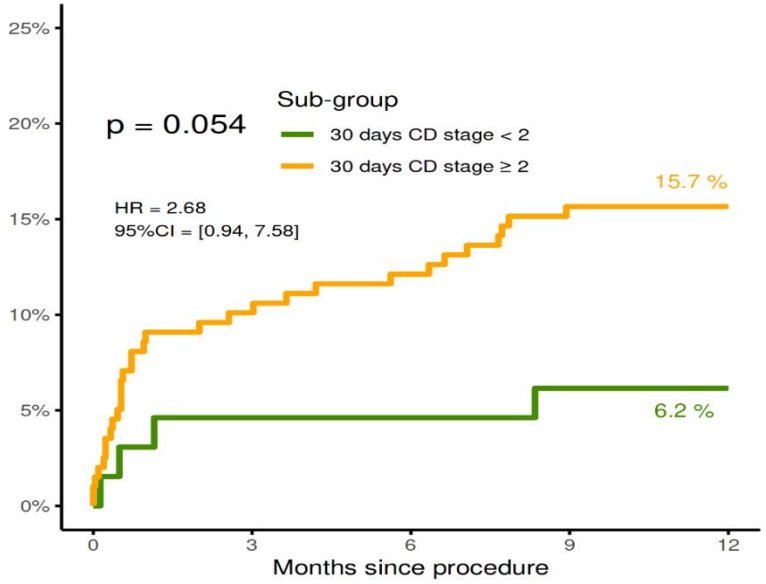
CD Stage 0 Stage 1 Stage 2 Stage 3 Stage 4

Association between Echo Parameters at 30 Days and Primary Clinical Outcome at 1 year (TAVI + SAVR)

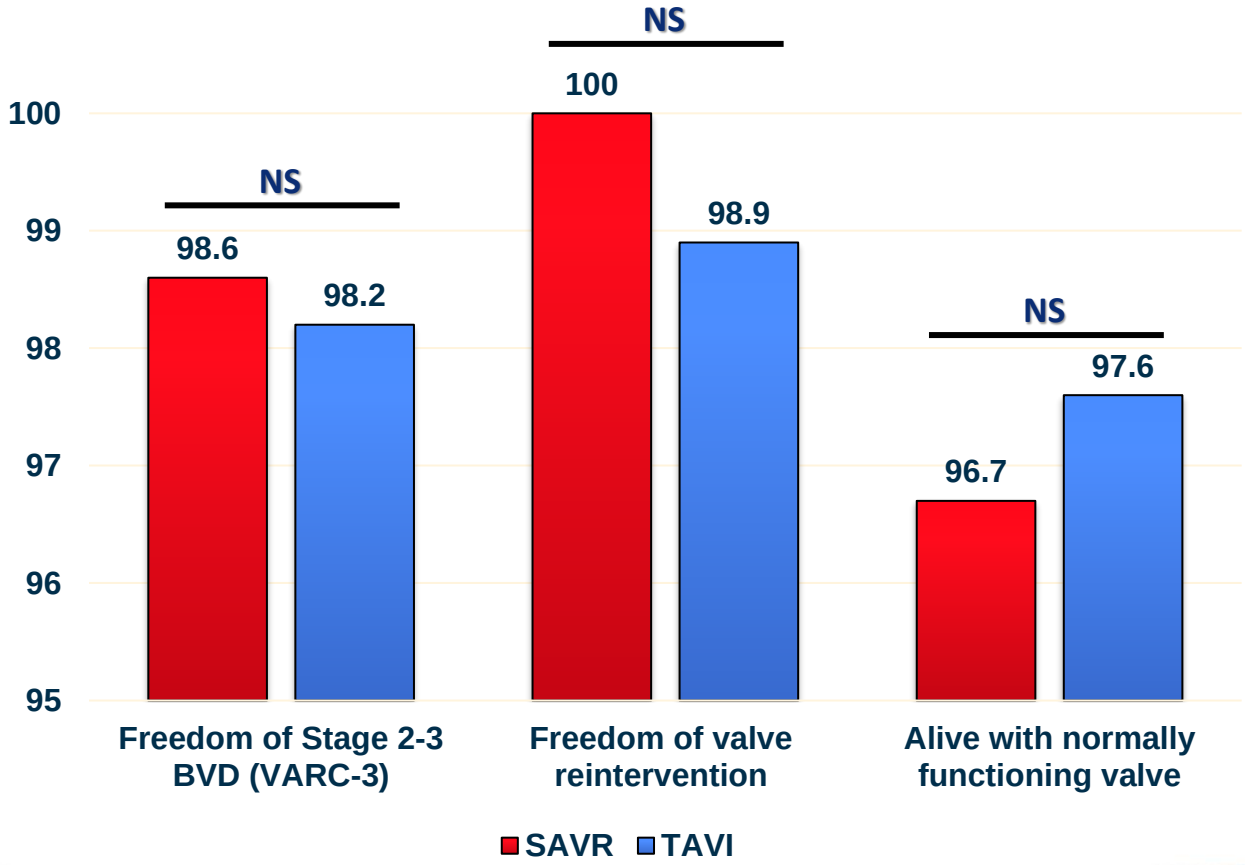
Intended valve hemodynamic performance



Cardiac Damage Stage ≥2



Bioprosthetic Valve Dysfunction at 1 Year



Conclusions (1)

RHEIA

Among women with severe AS:

- Both TAVI and SAVR achieved excellent valve hemodynamic results with low and similar rates of moderate paravalvular AR (<1%) an severe PPM (<3%).
- SAVR was associated with lower rates of high residual gradients and mild paravalvular AR, and less residual LV hypertrophy but similar improvements in LV diastolic & systolic function.
- The higher rate of residual LV hypertrophy with TAVI appears to be related to the higher rate of mild paravalvular AR.
- TAVI was associated with better RV systolic function and RV-PA coupling, and better evolution of cardiac damage stage at 1-year.

Conclusions (2)

- The rates of hemodynamic valve deterioration and reintervention were low (< 2%) in both groups with ~97% of patients being alive with a normally functioning valve at 1-year.
- Non-intended valve hemodynamic performance and cardiac damage stage ≥2 were associated with increased risk of the primary endpoint.

RHEIA

Thank You!

48 Clinical Sites - 443 Patients - 12 Countries

Top 10 enrolling sites

1. *Clinique Pasteur, Toulouse, France (Tchétché Didier, Berthoumieu Pierre, 31 pts.)*
2. *St Antonius Ziekenhuis Nieuwegein, Nieuwegein, The Netherlands (Swaans Martin, Timmers Leo, 29 pts.)*
3. *Universitätsklinik der Ruhr-Universität Bochum Herz- und Diabeteszentrum Nordrhein-Westfalen, Bad Oeynhausen, Germany (Rudolph Tanja, Bleiziffer Sabine, 27 pts.)*
4. *Hôpital Cardiologique du Haut-Lévêque, Bordeaux, France (Leroux Lionel, Modine Thomas, 25 pts.)*
5. *Leids University Medical Center, Leiden, The Netherlands (Bax Jeroen, Frank van der Kley, 22 pts.)*
6. *CHU Rouen - Hopital Charles Nicolle, Rouen, France (Eltchaninoff Hélène, 18 pts.)*
7. *CHU Rennes - Hopital de Pontchaillou, Rennes, France (Auffret Vincent, Tomasi Jacques, 18 pts.)*
8. *Universitätskliniken Innsbruck, Innsbruck, Austria (Bonaros Nikolaos, Stastny Lukas, 17 pts.)*
9. *Allgemeines Krankenhaus der Stadt Wien, Vienna, Austria (Hengstenberg Christian, Andreas Martin, 17 pts.)*
10. *CHU Montpellier - Hopital Arnaud de Villeneuve, Montpellier, France (Leclercq Florence, Gandet Thomas, 16 pts.)*

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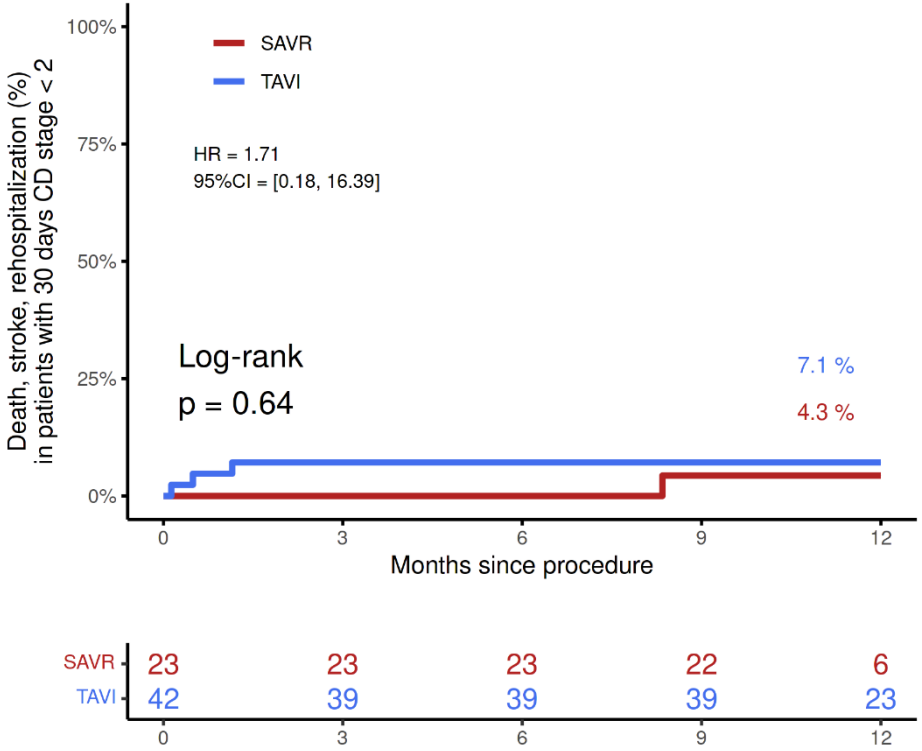
Study Limitations

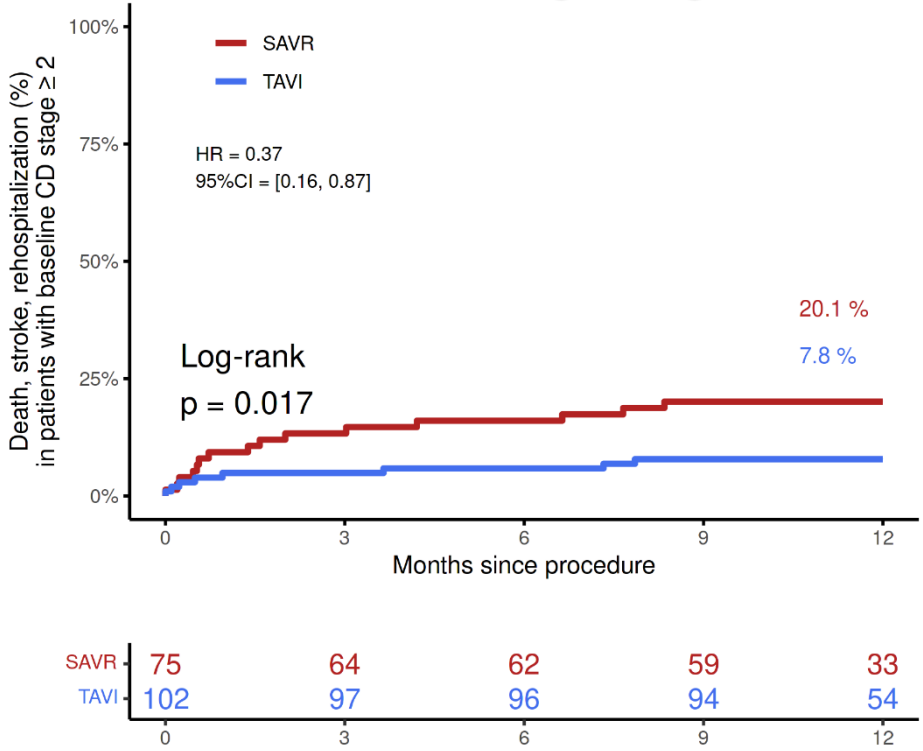
- RHEIA trial was of limited size
- Women with unicuspid, biscuspid, or non-calcified valves were excluded
- Concomitant procedures were performed in 13.2 % of the surgical patients
- The findings relate to a third-generation balloon-expandable valve system and cannot be extrapolated to other valve types
- The recruitment period was long (~3.5 years) because of COVID pandemic
- Echocardiographic data were missing in 15% of the study cohort
- TAPSE was the sole parameter used to assess RV function
- The duration of the follow-up is limited to 1-year

Association between Echo Parameters at 30 Days and Primary Clinical Outcome at 1 year: Subgroup Analysis

Cardiac Damage Stage < 2

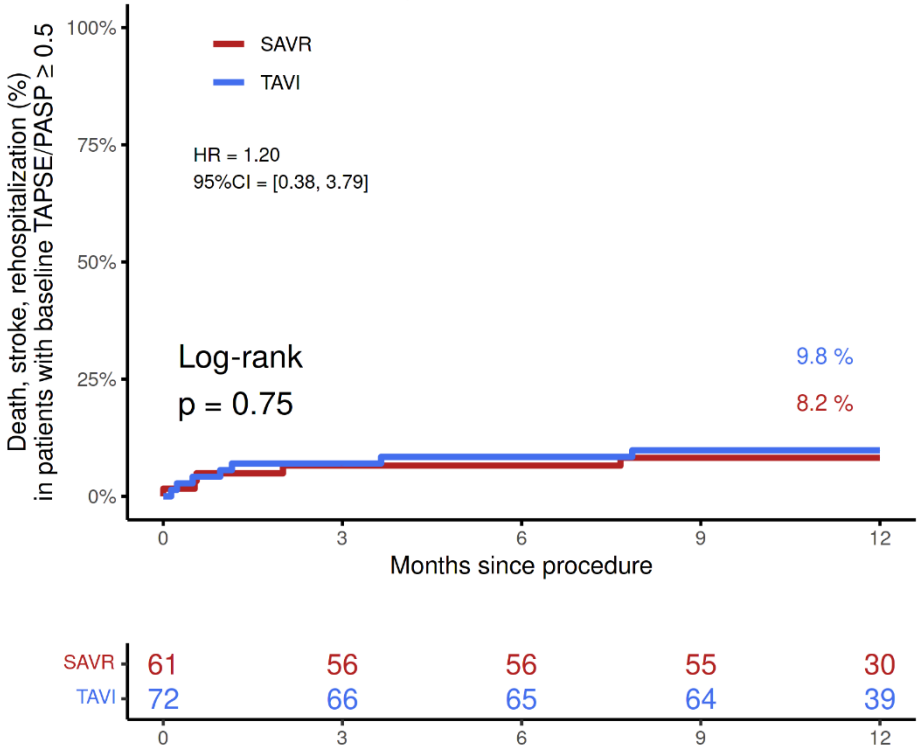


Cardiac Damage Stage ≥ 2



Association between Echo Parameters at 30 Days and Primary Clinical Outcome at 1 year: Subgroup Analysis

TAPSE / PASP ≥ 0.50



TAPSE / PASP < 0.50