Cardiac Damage and Quality of Life After AVR: Results from the PARTNER Trials

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on behalf of the PARTNER Trial Investigators

Disclosures

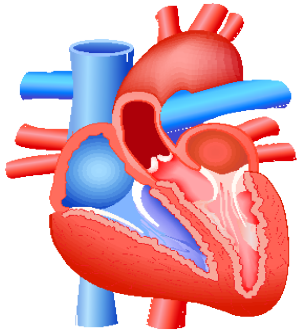
Abbott Vascular: Consultant, advisor, speaker Fees; Abiomed: Consultant, advisor, speaker fees; BioTrace Medical: Consultant, advisor, speaker Fees; Boston Scientific: Consultant; CARANX Medical: Consultant; Cardiovascular System Inc.: Consultant, PI Eclipse Trial; Edwards LifeSciences: Consultant, advisor, speaker fees, proctor, research grant, PI EARLY-TAVR trial, PI PROGRESS trial; GE Healthcare: Consultant; iRythm Technologies: Consultant; Medtronic: Consultant, advisor, speaker fees; Opsens: Consultant; Pi-Cardia: Equity, consultant; Puzzle Medical: Equity, consultant; Saranas: Equity, consultant; Shockwave: Consultant, speaker fees; Siemens: Consultant; Soundbite Medical Inc.: Equity, consultant; Teleflex: Consultant; 4C Medical: Consultant, PI Feasibility study

Background

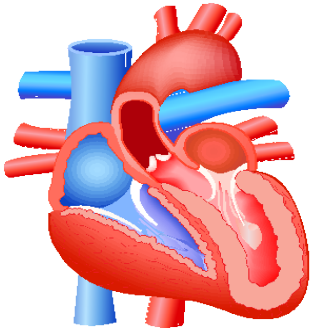
- Previously, we described a novel AS staging classification based on the extent of extra-valvular cardiac damage before AVR.
- Specific, well-validated echo parameters are used to stratify patients into 5 different AS disease stages.

Généreux et al. Eur Heart J 2017 Dec 1;38(45):3351-3358.

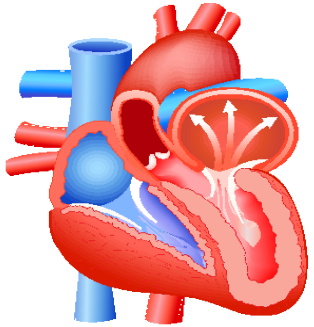
Staging Classification of Patients with AS



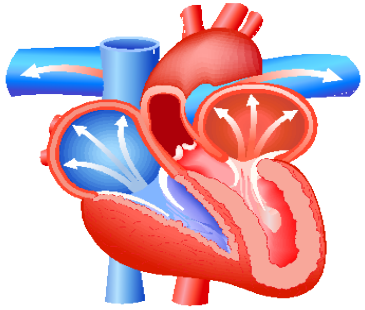
Stage 0 No Damage



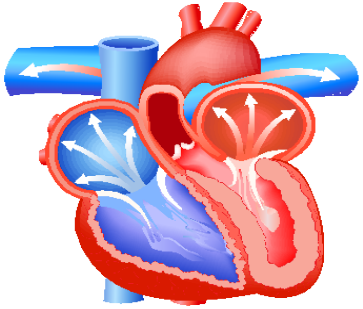
Stage 1 LV Damage
Increased LVMI > 115 g/m^2 Male > 95 g/m^2 Female
E/e' > 14
LVEF < 50%



Stage 2 LA/Mitral damage
Indexed LA vol > 34 mL/m^2
≥ Moderate MR
Atrial Fibrillation



Stage 3 PA/Tricuspid damage
PAS ≥ 60mmhg
≥ Moderate TR

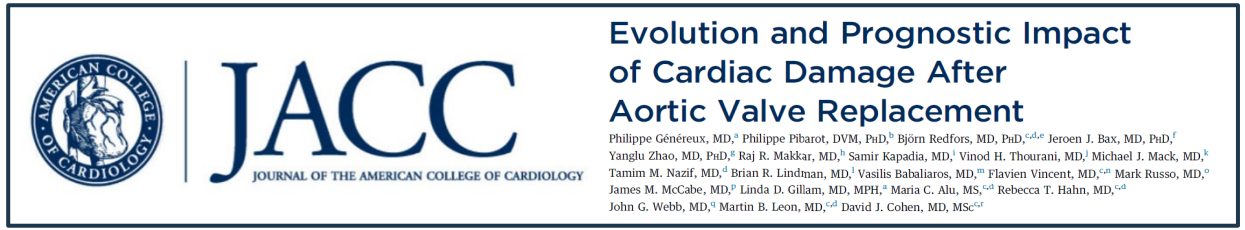


Stage 4 RV damage
≥ Moderate RV dysfunction

Généreux et al. Eur Heart J 2017 Dec 1;38(45):3351-3358.

Background

- The extent of cardiac damage was shown to be strongly and positively associated with mortality and adverse events at 1-year post-AVR.
- Worsening AS stage at 1-year increases the risk of death or heart-failure rehospitalization at 2 years.



Généreux et al. J Am Coll Cardiol. 2022 Aug, 80 (8) 783–800. ePub May 2022.

Objectives

- The impact of AVR and cardiac damage stage on quality-of-life outcomes is unknown.
- We sought to describe the association of AS stage with health status before and after AVR.

Methods

- Patients with severe, symptomatic AS undergoing surgical or transcatheter AVR from the PARTNER 2A, 2B, and 3 trials were pooled and stratified by extra-valvular cardiac damage stage via TTE.
- Health status outcomes were evaluated using the 23-item KCCQ-OS score.
- Independent association of baseline cardiac damage stage with 1-year outcomes was assessed using multivariable logistic regression analysis.

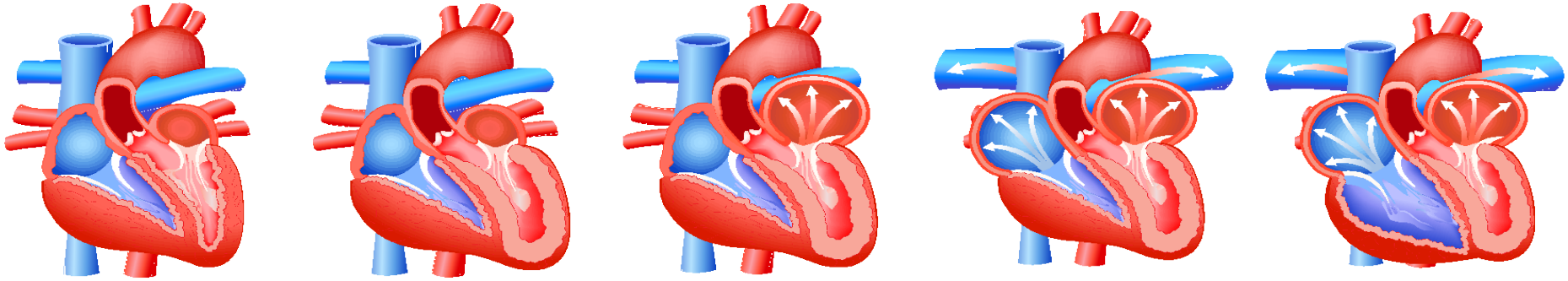
Patient Distribution

Patients with severe AS undergoing AVR in PARTNER 2A, 2B, and 3 trials
N = 3401

Patients with complete echo staging data available at baseline
N = 1974

- **Inoperable/ Extreme risk (P2B)** N = 342 (17.3%)
- **Intermediate risk (P2A)** N = 1071 (54.3%)
- **Low risk (P3)** N = 561 (28.4%)
- **TAVR** N = 1180 (59.8%)
- **SAVR** N = 794 (40.2%)

Staging Classification of Patients with AS



Stage 0	Stage 1	Stage 2	Stage 3	Stage 4
N=121 (6.1%)	N=287 (14.5%)	N=1014 (51.4%)	N=412 (20.9%)	N=140 (7.1%)

Total N = 1974 patients

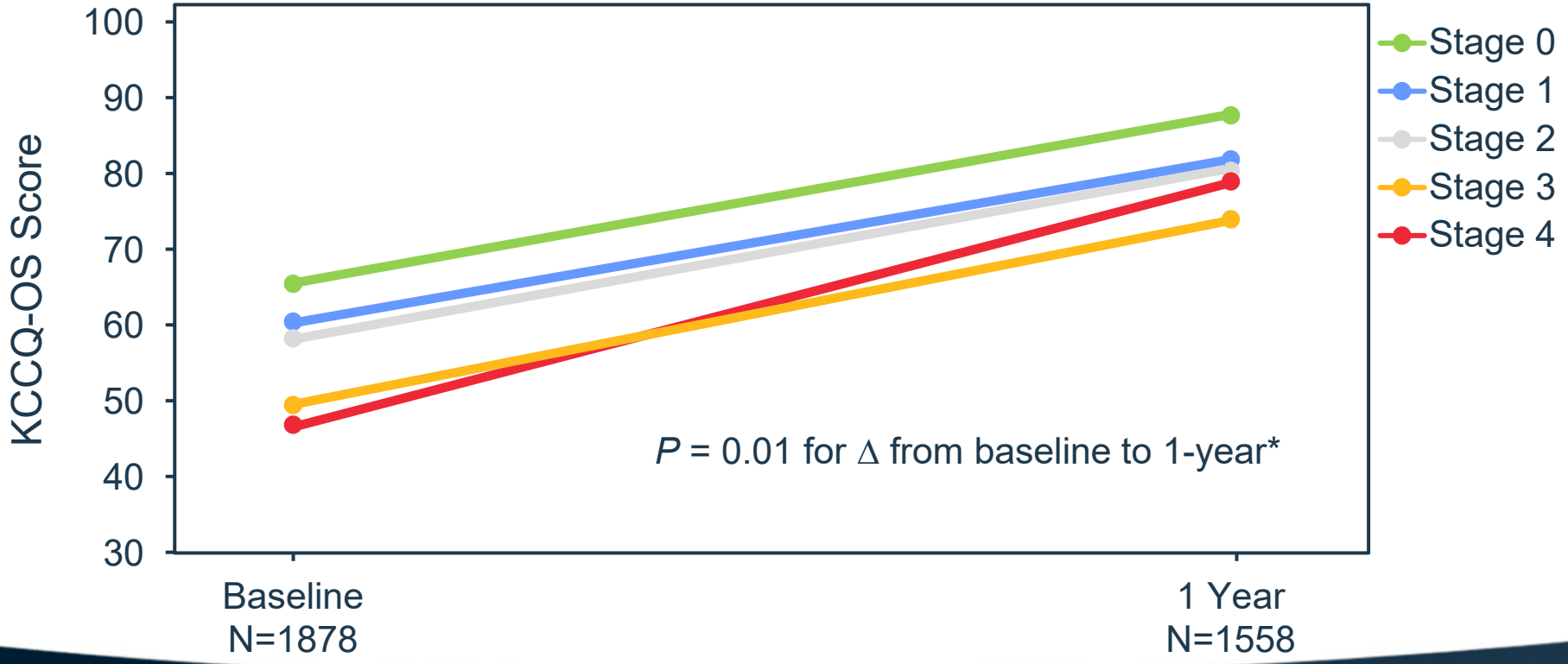
KCCQ-OS Score
According to Baseline Cardiac Damage

KCCQ-OS Score	Stage 0 (N=121)	Stage 1 (N=287)	Stage 2 (N=1014)	Stage 3 (N=412)	Stage 4 (N=140)	*P* value
Baseline	65.6 ± 21.5	60.6 ± 23.9	58.4 ± 22.7	49.6 ± 23.3	47.0 ± 24.9	<0.0001
1-Year	87.8 ± 13.1	82.0 ± 19.2	80.5 ± 19.1	74.1 ± 21.2	79.1 ± 19.7	<0.0001
Δ at 1-Year	21.8 ± 21.7	20.0 ± 21.9	20.6 ± 21.4	22.7 ± 21.7	28.4 ± 28.4	0.011

values are mean ± SD

*P value from chi square

ΔKCCQ-OS Score According to Baseline Cardiac Damage



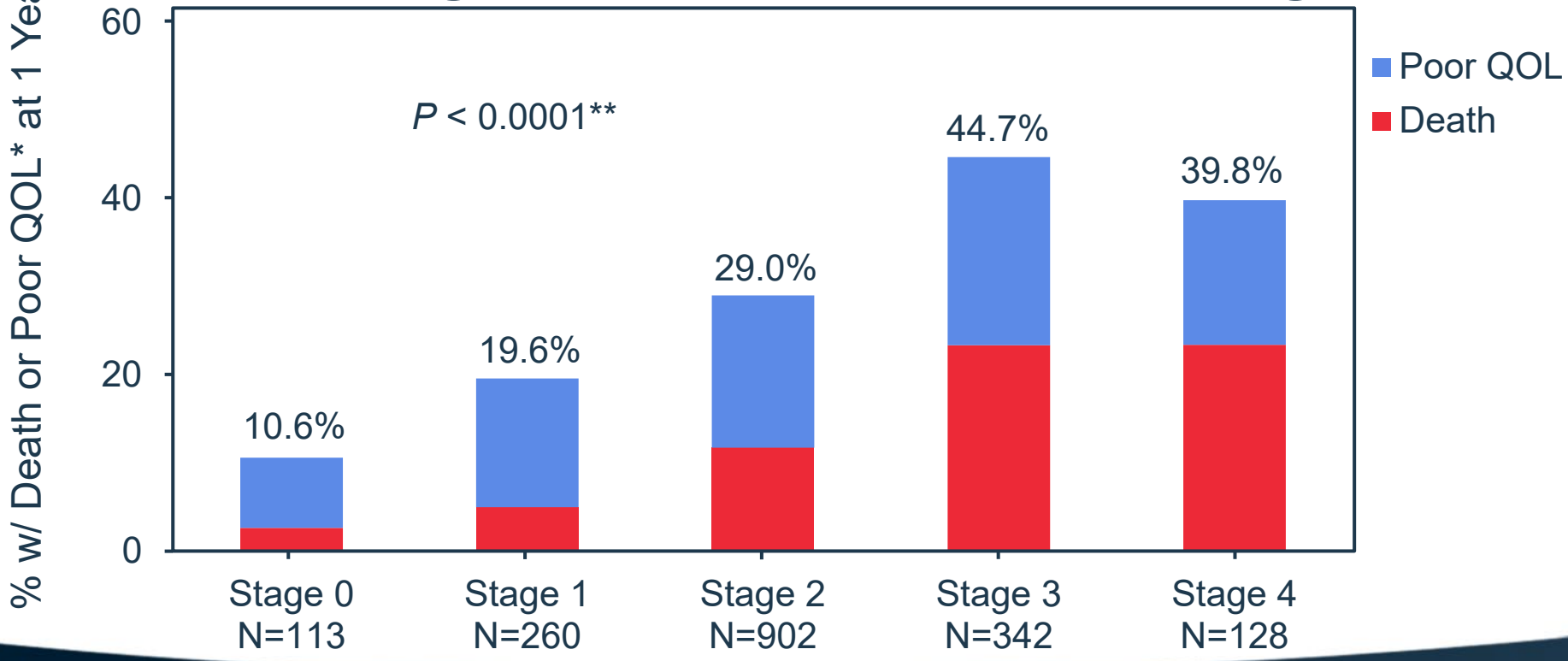
*P value from ANOVA

Health Status at 1 Year
According to Baseline Cardiac Damage

	Stage 0 (N=121)	Stage 1 (N=287)	Stage 2 (N=1014)	Stage 3 (N=412)	Stage 4 (N=140)	*P* value
Composite	10.6%	19.6%	29.0%	44.7%	39.8%	<0.0001
Death	2.5%	4.5%	10.5%	19.4%	21.4%	<0.0001
KCCQ-OS <60	3.5%	13.9%	16.4%	25.8%	16.2%	<0.0001
Decline in KCCQ-OS ≥10	5.5%	4.9%	6.1%	5.0%	8.2%	0.76

**P value from chi square*

Health Status at 1 Year
According to Baseline Cardiac Damage



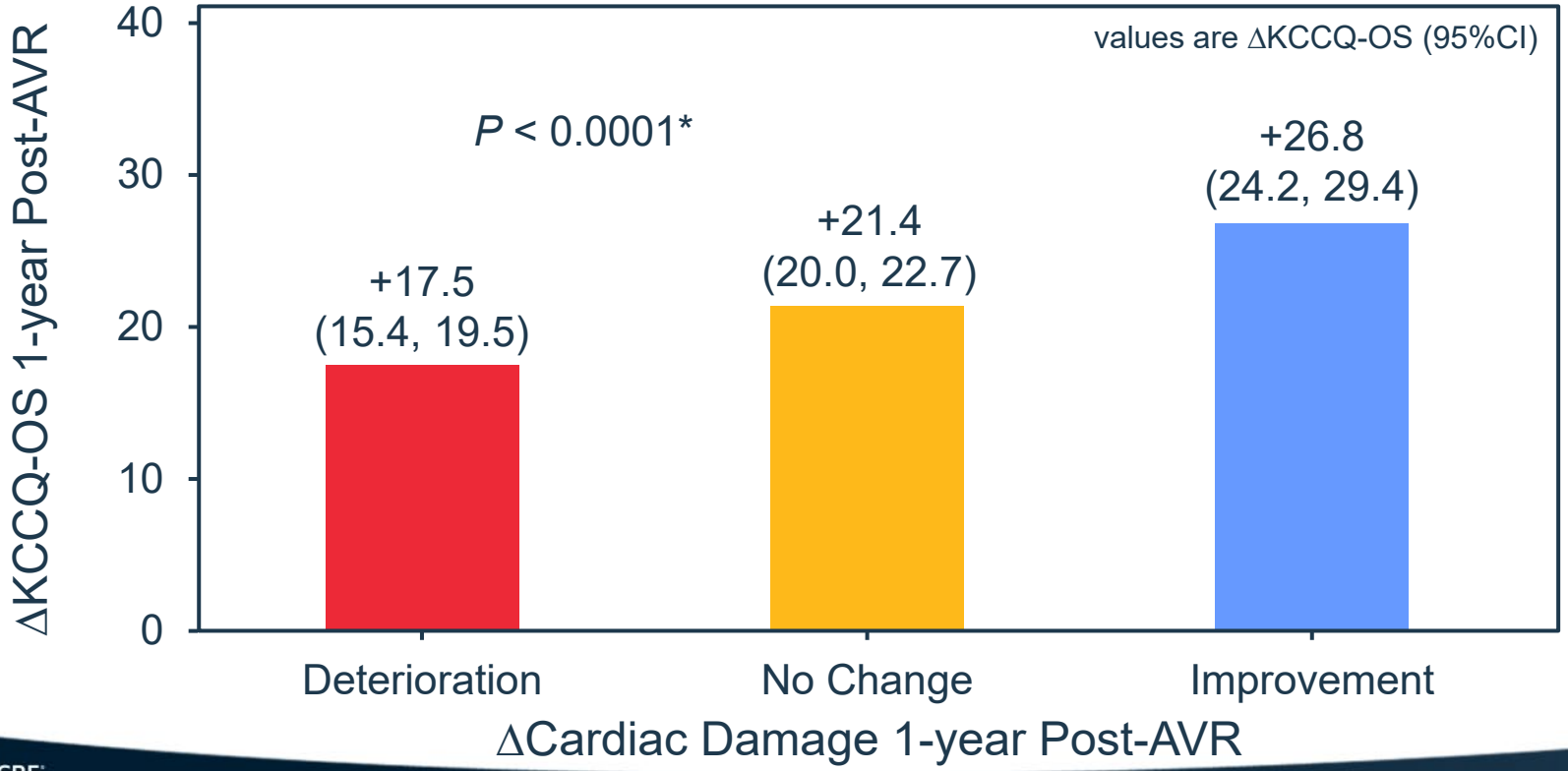
*Poor QOL defined as KCCQ-OS <60 or decline in KCCQ-OS ≥10
**P value from chi square

Results

- Multivariable modeling showed that ***each 1-stage increase*** in baseline cardiac damage was associated with a ***24% increase in the odds of a poor outcome at 1 year*** [OR (95% CI) = 1.24 (1.09-1.41); p=0.001].
- Of 1120 patients with evaluable echos at 1-year post-AVR, change in cardiac damage stage was as follows:
  - 15.6% improved
  - 57.9% unchanged
  - 26.5% worsened

KCCQ-OS Score 1-year Post-AVR

by ΔCardiac Damage Stage



*Adjusted for baseline KCCQ-OS and baseline stage of cardiac damage (ANCOVA)

Limitations

- Many patients excluded due to insufficient or missing data.
- Randomized, highly-selected study population limited to patients with severe, symptomatic, calcific AS.
- New occurrence or worsening of existing cardiac damage could be a result of conditions unrelated to AS.
- Unclear if a particular component within a cardiac damage stage is of more or less prognostic importance.

Conclusions

- Cardiac damage classified by baseline AS stage has an important impact on health status, both cross-sectionally and after AVR.
- Regression of cardiac damage within 1-year post-AVR is associated with greater health status improvement compared to patients whose cardiac damage stage was unchanged or worsened.
- Detecting and addressing AS before irreversible cardiac damage develops may improve long-term outcomes after AVR.
- Longer follow-up is needed to better characterize the impacts of AS stage and AVR on quality-of-life outcomes.