Transcatheter versus medical treatment of symptomatic severe tricuspid regurgitation: a propensity score matched analysis

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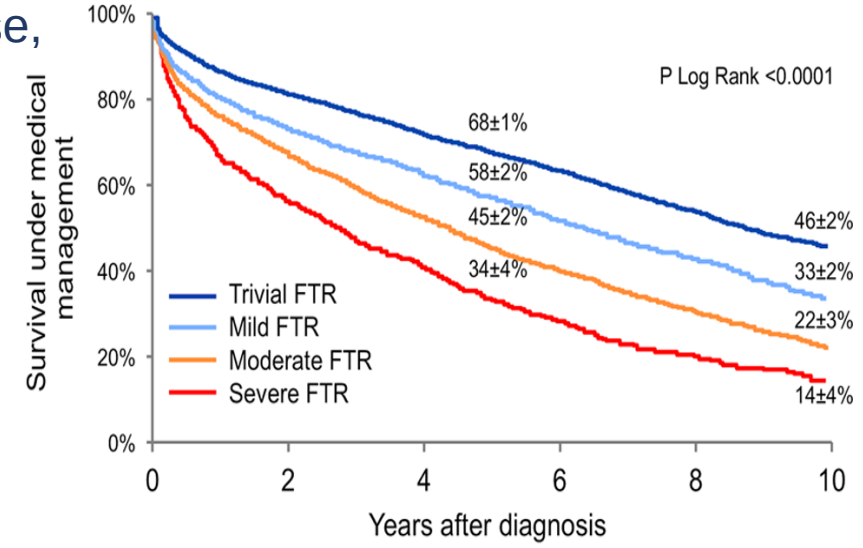
Disclosure Statement of Financial Interest

Within the past 12 months, I or my spouse/partner have had a financial interest/arrangement or affiliation with the organization(s) listed below:

Affiliation/Financial Relationship	Company
Consulting Fees/Honoraria	Abbott Boston Scientific Edwards Lifesciences 4tech CoreMedic

Background

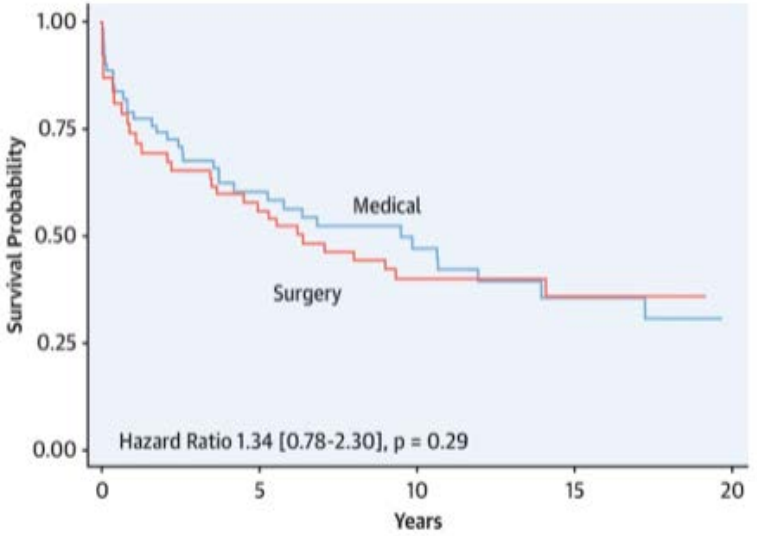
- High prevalence of TR in the cardiological population (concomitant left-side heart disease, chronic atrial fibrillation, or pulmonary hypertension setting)
- For long considered a benign valve disease, but highly impact the survival
- Uncertainty in regard to the clinical efficacy of TR therapies



Benfari G. et al. Circulation. 2019 Jul 16;140(3):196-206

Background

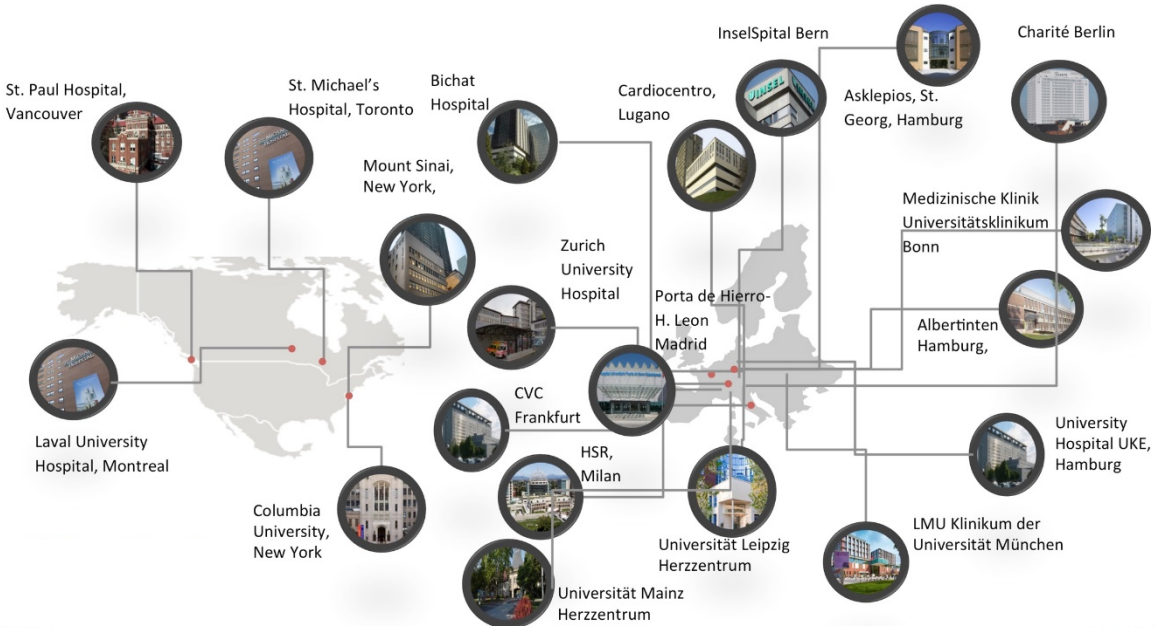
- TR surgical treatment is associated to high operative mortality, suboptimal long-term survival, and frequent TR recurrence after repair.
- Uncertainty in regard to the clinical efficacy of TR therapies (currently transcatheter therapies are not included in the guidelines).
- Lacking RCTs



Axtell, A.L. et al. J Am Coll Cardiol. 2019;74(6):715-25.

TriValve Registry

- The TriValve International Registry represents so far the largest multicenter, multi-devices series of patients with symptomatic severe TR who underwent transcatheter tricuspid valve interventions (TTVI)



Aim

- Comparing outcomes of TTVI in high-risk patients (TriValve registry) to a control group of similar patients under conservative treatment with GDMT

Methods

- The control cohort of patients with severe TR was formed by consecutive patients evaluated at Mayo Clinic, Rochester, Mn, USA and Leiden University Medical Center, The Netherlands

- Exclusion criteria were previous tricuspid valve surgery or intervention, and iatrogenic (pacemaker lead related) TR

- Patients in the TTVI cohort (TriValve registry) were matched with controls using propensity scores (distance ± 0.2 SD). The variable adopted to calculate propensity score were age, Euroscore II, and pulmonary pressure level

Methods

- Primary endpoint was mortality from any cause or rehospitalization for heart failure (HF)

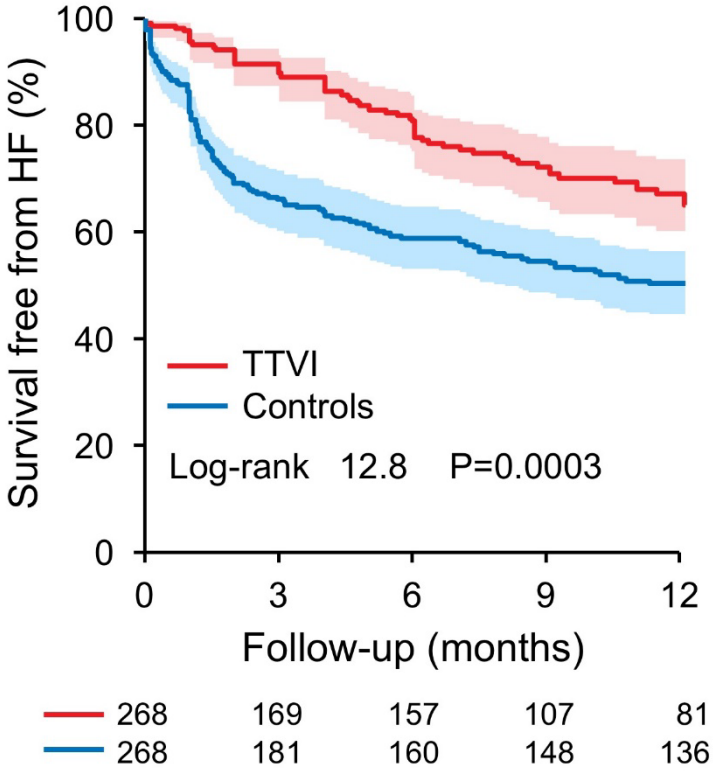
- Secondary endpoint was overall mortality. Follow-up data were collected for patients up to 12 month

- TTVI procedural success was defined as patient alive at the end of the procedure, with device successfully implanted, delivery system retrieved and residual TR <3+

Results

	Overall population N=1652			Propensity matched cohort N=536		
	TTVI N=472	Controls N=1179	P-value	TTVI N=268	Controls N=268	P-value
Age, y±SD	77±8	76 ±13	0.07	77±8	76 ±13	0.2
Women, %	55%	63%	0.007	56%	59%	0.4
TR of functional etiology	90%	96%	0.0004	90%	95%	0.1
Left ventricular EF, %	50 ±13	49 ±17	0.2	49±15	50 ±15	0.2
Left ventricular EF <35%, %	18%	26%	0.0006	22%	21%	0.7
Euroscore II, (%)	10.5±11.2	17.9±11.7	<0.0001	12±11	13±9	0.6
Right ventricular dysfunction	34%	20%	<0.0001	37%	29%	<0.0001
S-PAP, mmHg	40±15	52±15	<0.0001	44±14	43±14	0.3
Pulmonary hypertension, %	27%	50%	<0.0001	34%	29%	0.2
NYHA III-IV, %	93%	39%	<0.0001	93%	23%	<0.0001
Mitral regurgitation > 2+	33%	18%	<0.0001	40%	17%	<0.0001
Atrial Fibrillation, %	83%	57%	<0.0001	82%	50%	<0.0001
Pacemaker or defibrillator, %	26%	5%	<0.0001	29%	12%	<0.0001

Results: Primary and secondary endpoint



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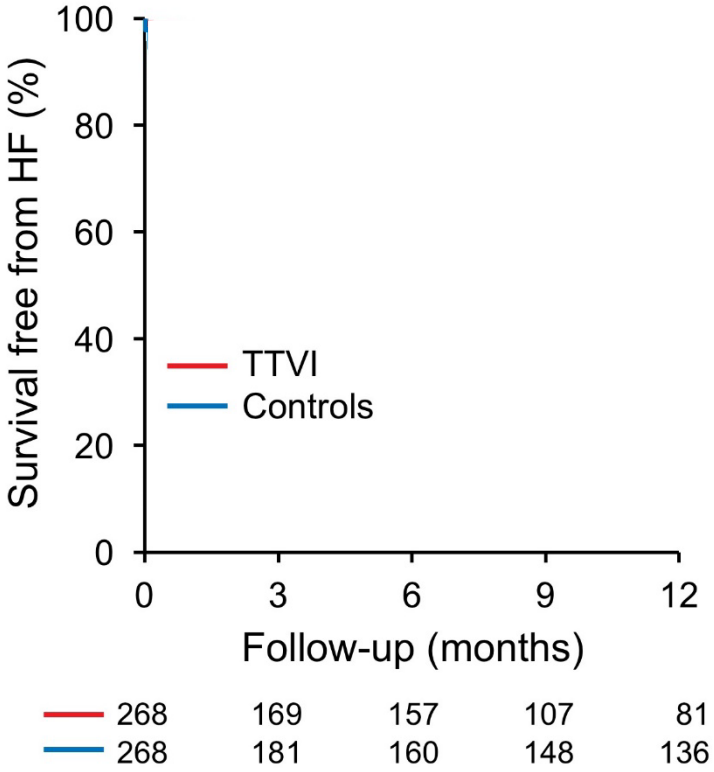

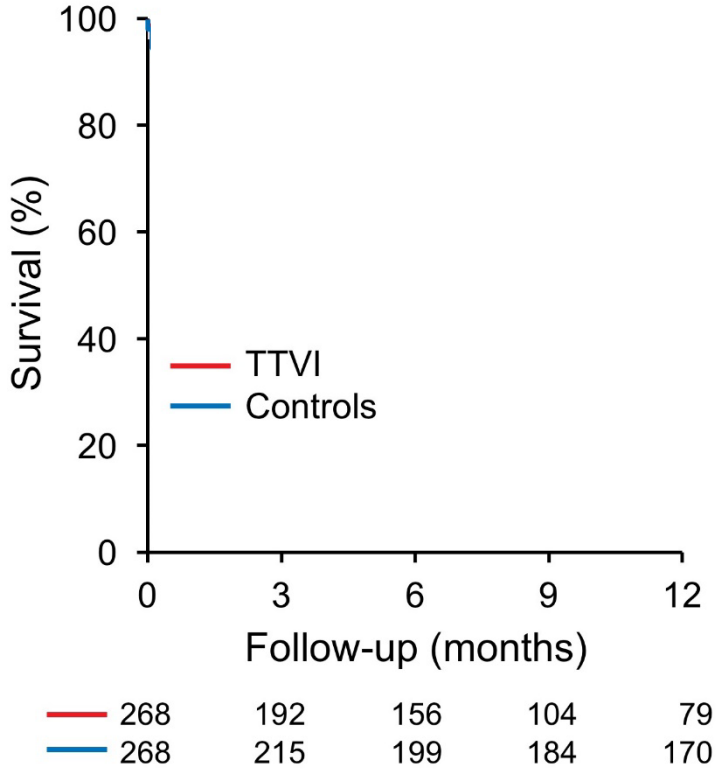

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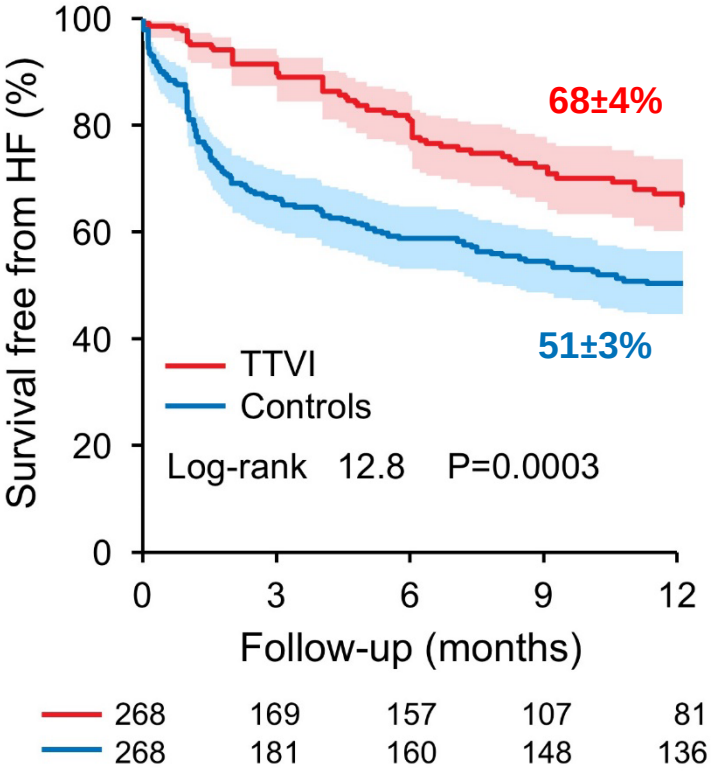

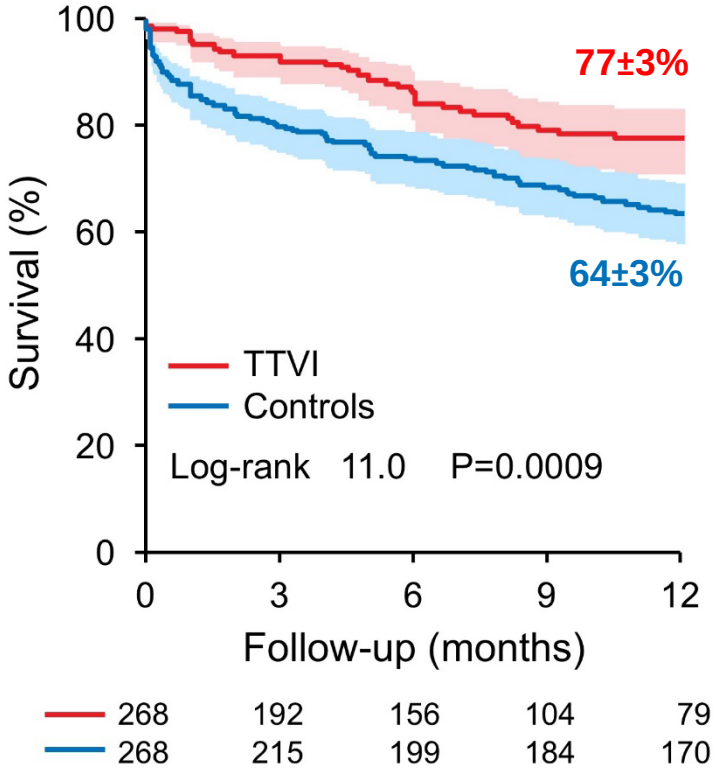

Results: Multivariable adjusted models

Model for control group	HR for death or heart failure hosp (primary endpoint)	P-value	HR for mortality (secondary endpoint)	P-value
1) Unadjusted	0.60 (0.46-0.79)	0.003	0.56 (0.39-0.79)	0.001

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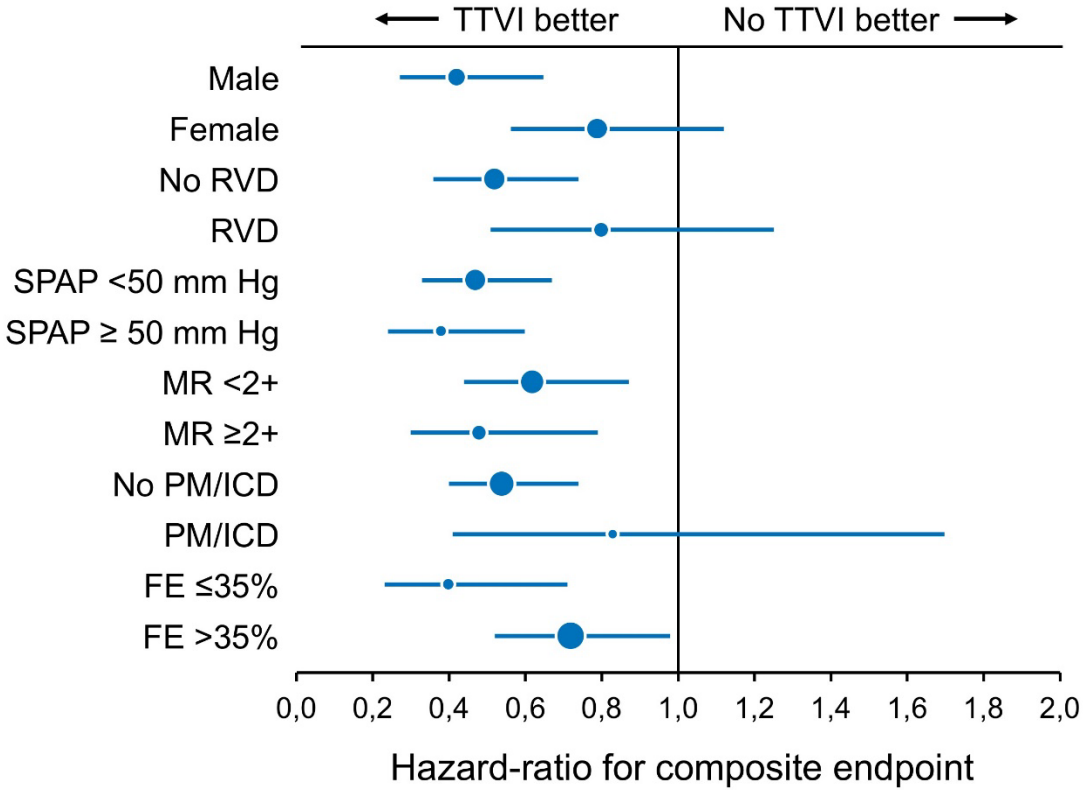
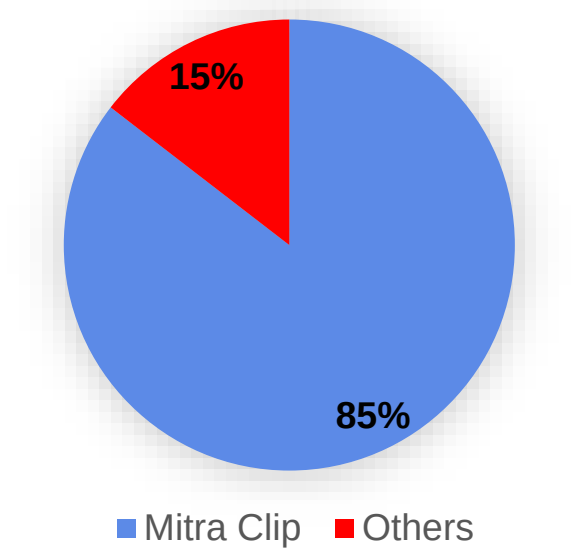
4) Adj for sex and NYHA, Afib, and RV dysf, MR>2+, PM/ICD	0.35 (0.23-0.54)	<0.0001	0.38 (0.23-0.63)	0.002

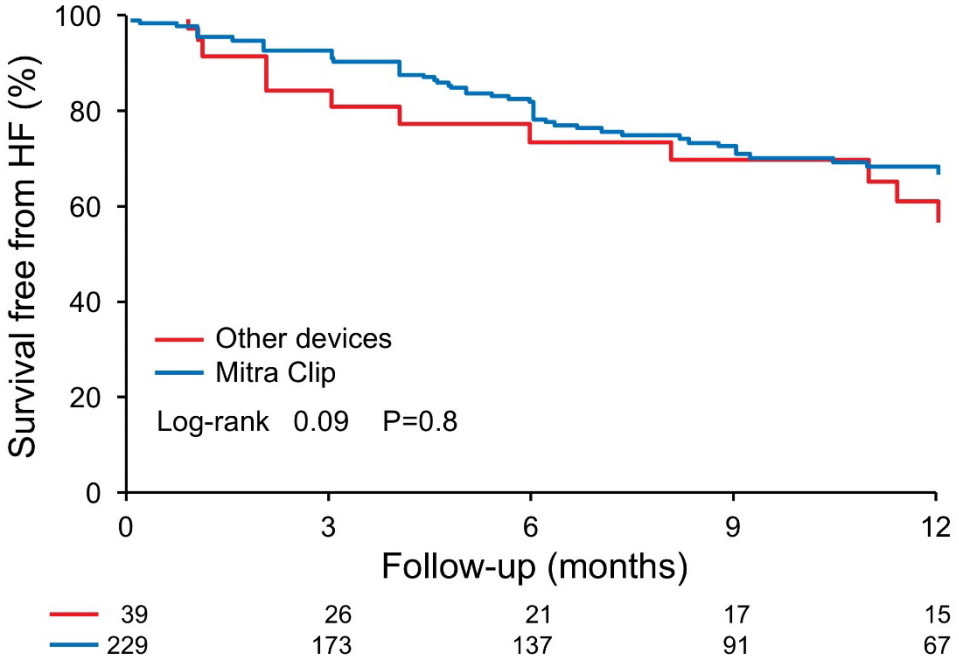
Results: subgroup analysis



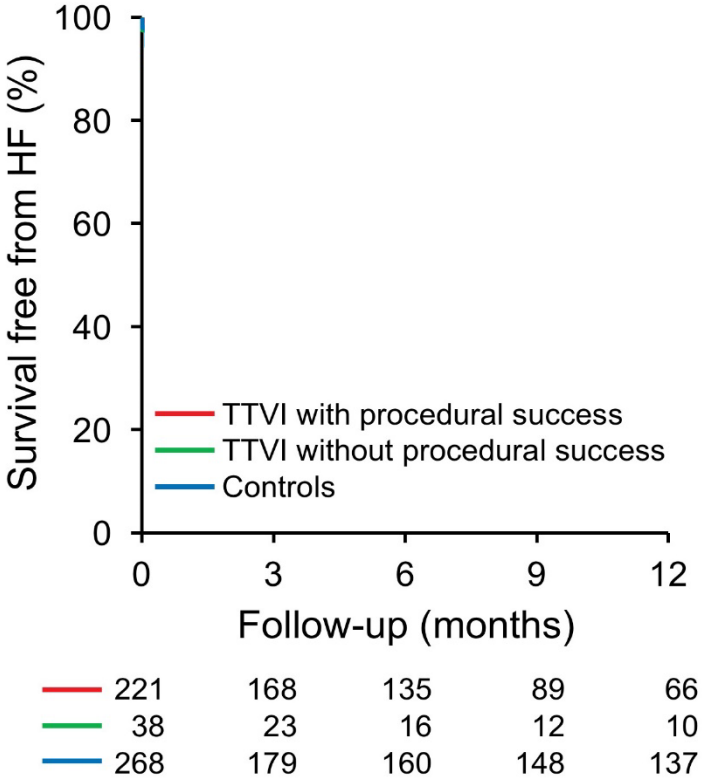
Results: TTVI device type

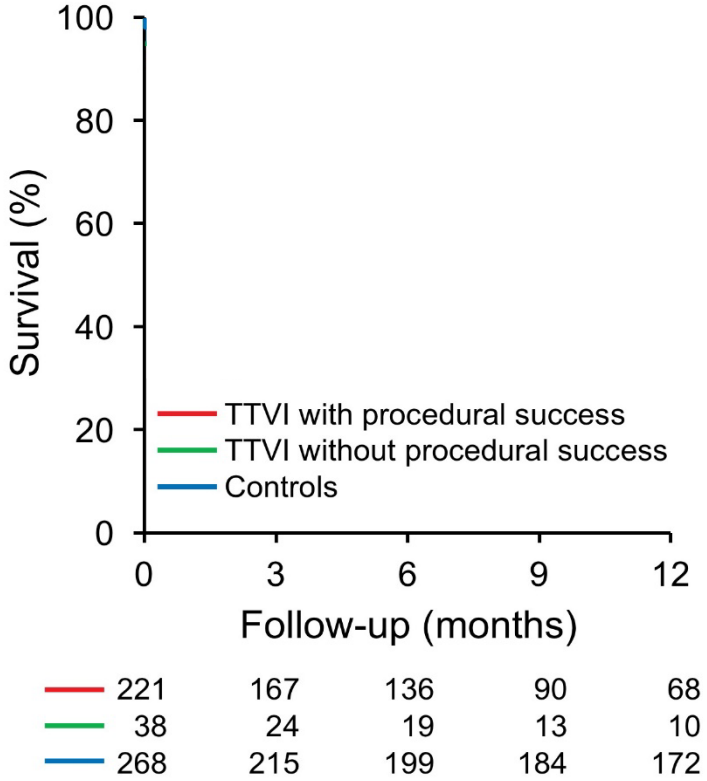
Total matched TTVI: 268



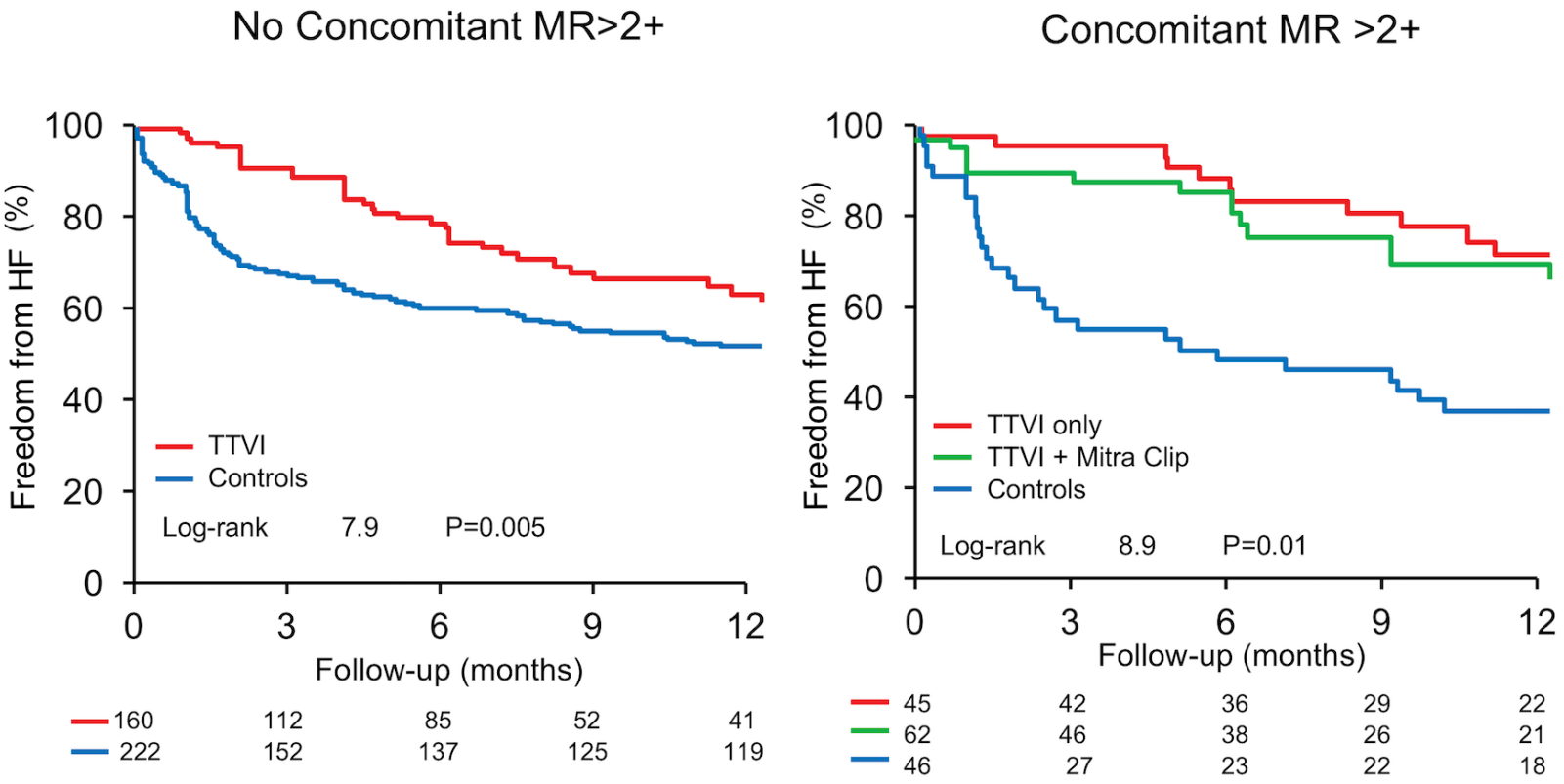


Results: Procedural success vs. residual TR





Results: impact of concomitant MR



Limitations of the study

- it is not a randomized trial and relevant confounders might not be represented in the risk-adjustment process
- Absence of Core-Lab
- A minority of patients had concomitant MR treatment
- Medical therapy for severe TR not standardised
- Highly selected patients in TTVI group

Conclusions

- **TTVI in high-risk patients with symptomatic severe TR as compared to medical treatment alone is associated to lower incidence of composite endpoint as well as lower all-cause mortality, at 1 year follow-up**

- **A significant difference was observed between patients undergoing TTVI with procedural success compared to those in whom procedural success was not achieved**

- **TTVI patients without a significant reduction in TR presented similar outcomes vs. control group, confirming the prognostic role of TR reduction in improving outcomes**