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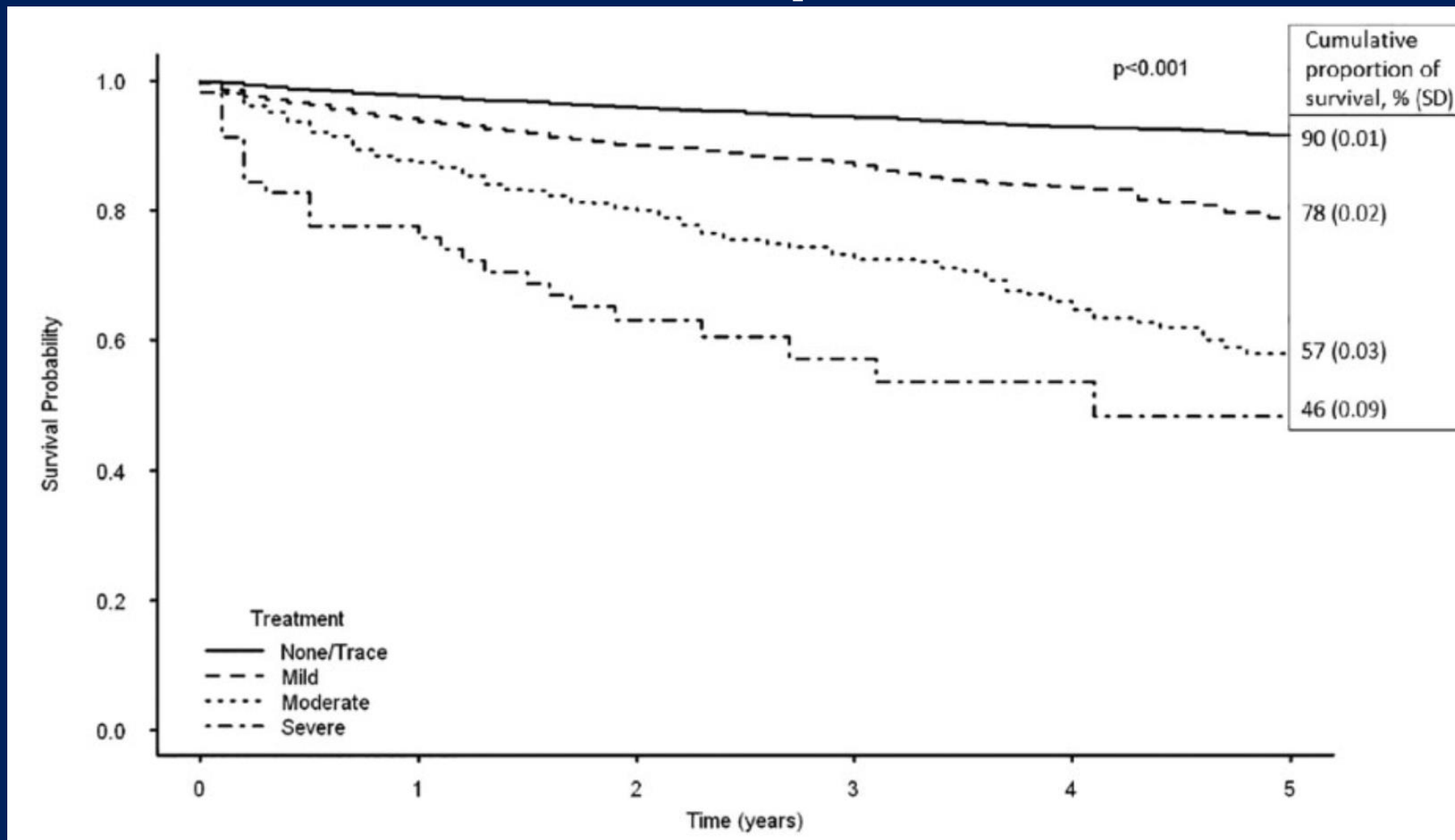
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Effects of ICD Leads on the Tricuspid Valve and Right Ventricle: A Randomized Comparison of Transvenous versus Subcutaneous Leads

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On behalf of the ATLAS Investigators

Tricuspid Regurgitation & Mortality in the General Patient Population



TR Following Transvenous Cardiac Device Leads

- Incidence 7%-45%
- Observational data
 - Extent to which natural history of underlying cardiac disease accounts for post-lead TR is unknown

Objectives

Primary

- To determine the effect of transvenous ICD on TR severity

Secondary

- To determine the effect of transvenous ICD on RV size and function

Avoid Transvenous Leads in Appropriate Subjects (ATLAS)

- RCT comparing subcutaneous ICDs (S-ICD) with transvenous ICDs (TV-ICD)
- Investigator-initiated study conducted at 14 Canadian sites
- Funded by Boston Scientific through an unrestricted research grant
- Boston Scientific did not have any input into this analysis

ATLAS Inclusion Criteria



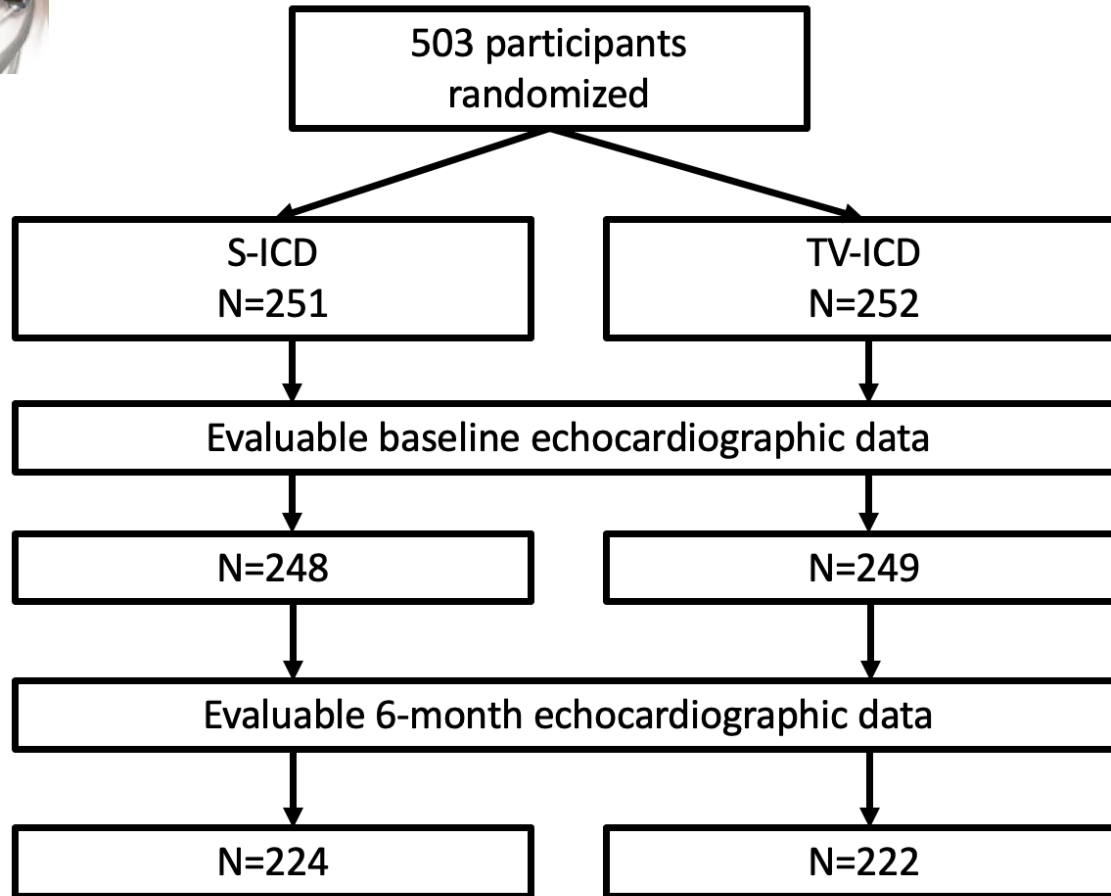
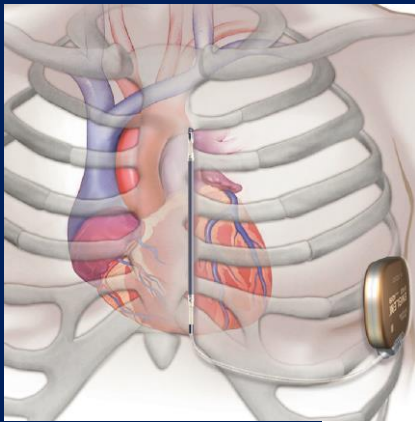
- Indication for primary or secondary prevention ICD
- Age <60 years or other risk factor for TV-lead complications
 - Cardiogenetic phenotype
 - Chronic hemodialysis
 - Prior lead removal for infection
 - Prior heart valve surgery
 - COPD

ATLAS Exclusion Criteria



- Contra-indication to TV-ICD or S-ICD
- Mechanical TV
- Fontan repair or intracardiac shunt
- Indication for pacing
- VAD
- PR >240ms
- Pregnancy

ATLAS



#HRS2023

Methods

- Standardized echocardiograms were performed according to a dedicated imaging protocol pre-ICD and at 6-months
- All echo analysis performed in the Core Laboratory, Population Health Research Institute, McMaster University by experts blinded to allocation (masking of leads visible in images was not feasible)

Methods

Primary Endpoint

TR quantified as none/trivial; mild; moderate; or severe

Secondary Endpoints

- RV basal diameter from AP4 view
- RV fractional area change
- RV function quantified as normal; mild, moderate or severely impaired based on all available echo data

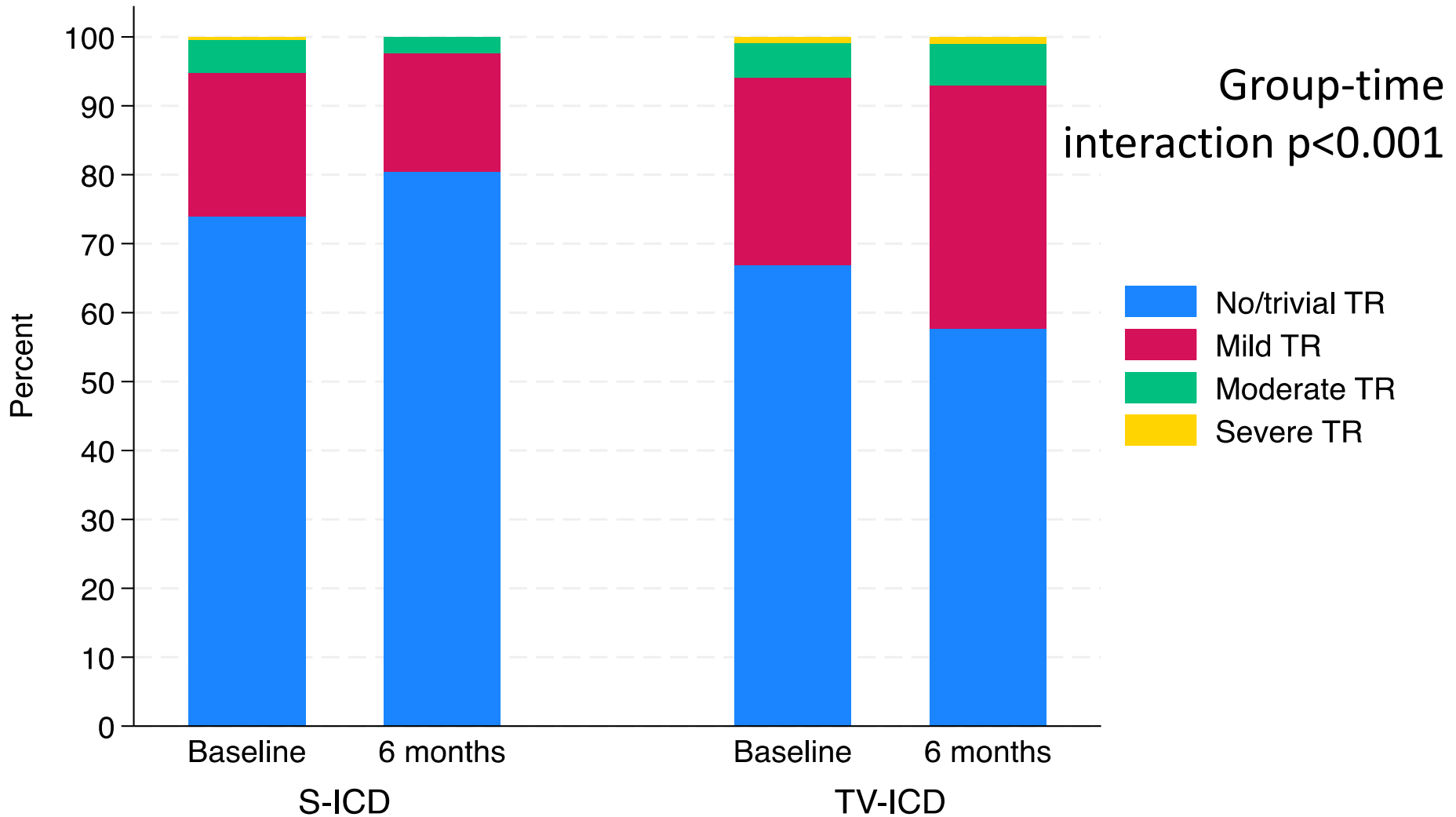
Baseline Clinical Characteristics

Characteristic	S-ICD N=251	TV-ICD N=250
Age, years	48±12	50±11
Male sex	76%	72%
Coronary artery disease	35%	38%
Dilated cardiomyopathy	22%	23%
Hypertrophic cardiomyopathy	18%	19%
RV cardiomyopathy	4%	4%
Heart failure	50%	46%
Hypertension	35%	35%
Diabetes	20%	20%

Baseline Echocardiographic Characteristics

Characteristic	S-ICD N=251	TV-ICD N=250
LVEF, %	45±19	46±18
Tricuspid regurgitation		
None/trivial	74%	67%
Mild	21%	27%
Moderate	5%	5%
Severe	<1%	1%
RV fractional area change, %	41±13	42±13
RV basal diameter, cm	3.8±0.8	3.8±0.7
RV systolic function		
Normal	73%	78%
Mildly impaired	12%	10%
Moderately impaired	12%	9%
Severely impaired	3%	3%

Changes in Tricuspid Regurgitation



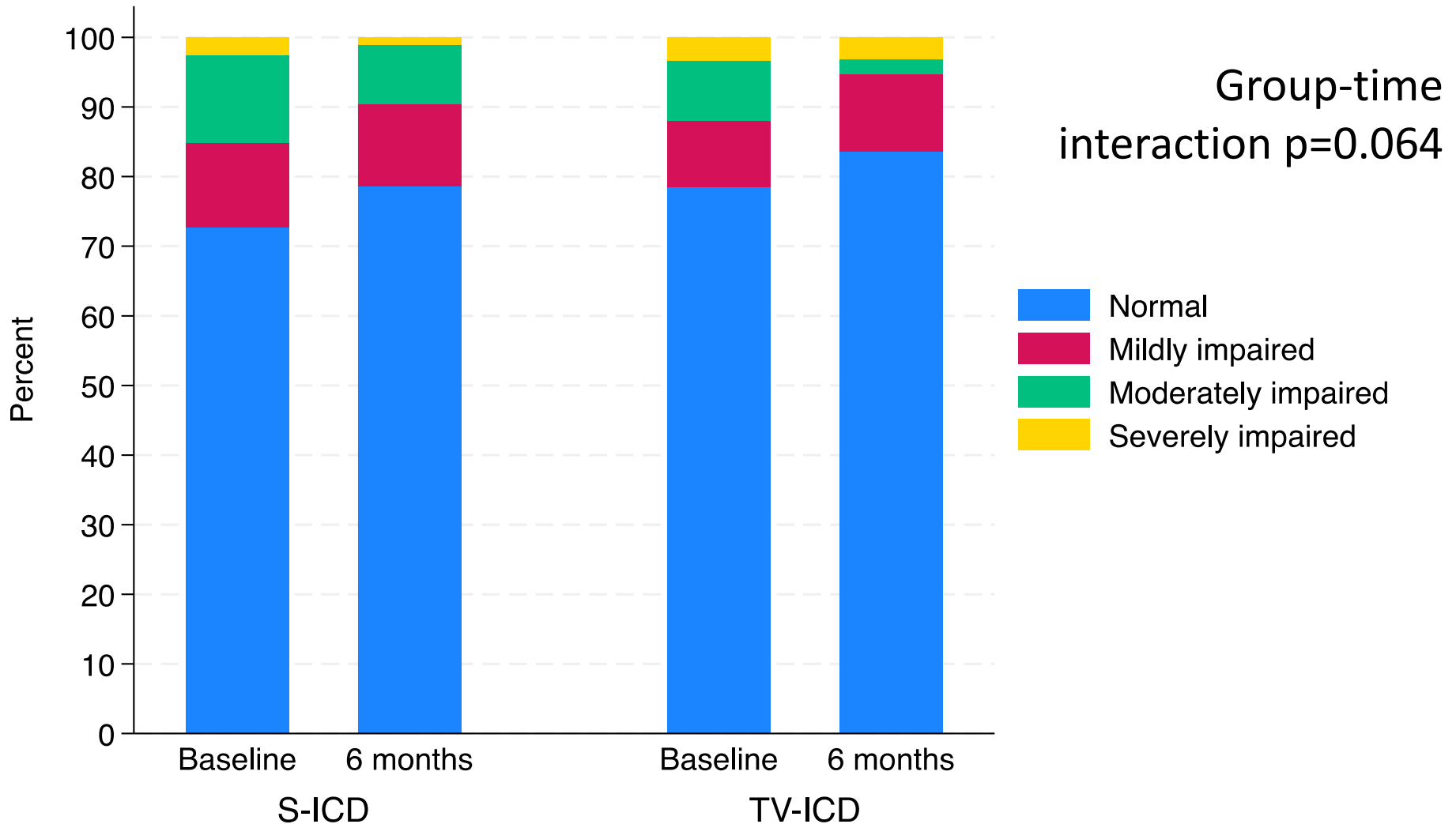
Changes in Tricuspid Regurgitation

	Baseline → 6-months	
	S-ICD	TV-ICD
Any TR	26% → 19%	32% → 42%
Moderate or severe TR	5% → 2%	6% → 7%

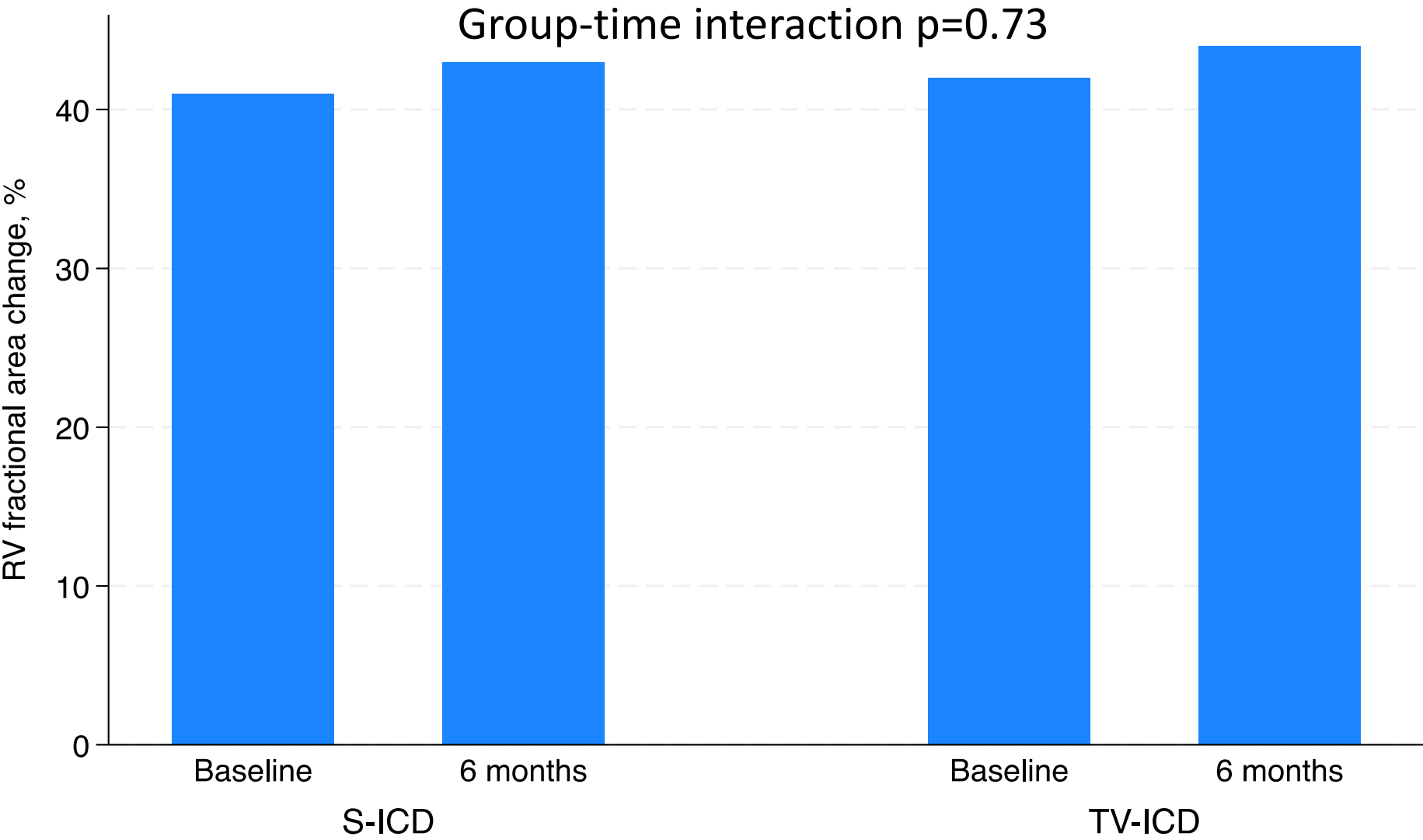
Odds ratio (95% CI) of ≥ 1 grade worsening TR in TV-ICD group:

7.2 (3.3-15.8), $p < 0.001$

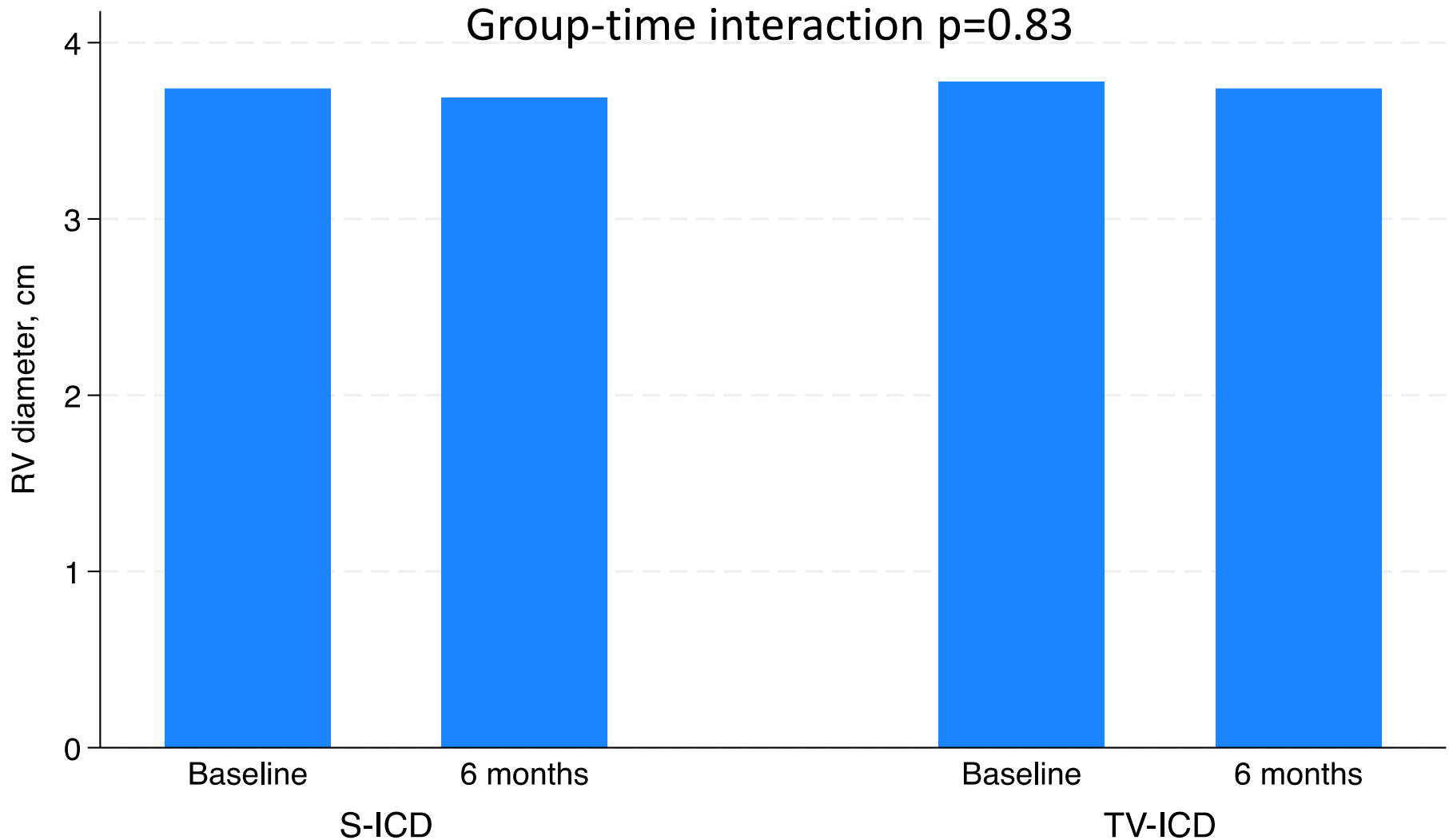
Changes in RV Systolic Function



Changes in RV Fractional Area Change



Changes in RV Basal Diameter



Subgroup Analyses

No evidence of heterogeneity according to baseline:

- Right ventricular size
- Right ventricular function
- Tricuspid regurgitation
- LVEF

Conclusions

Six months after implant, TV-ICD leads led to:

- 2x higher prevalence of any degree of TR
- 7x increase in the odds of worsening of TR
- 7% incidence of moderate or severe TR

Longer follow-up is needed to define impact on:

- Right ventricular size and function
- Clinical outcomes, including heart failure

Acknowledgements

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