Edwards PASCAL Transcatheter Valve Repair System

The CLASP TR Early Feasibility Study

30-day Multicenter Study Results

A Therapy Dedicated to Improving Symptomatic Tricuspid Regurgitation

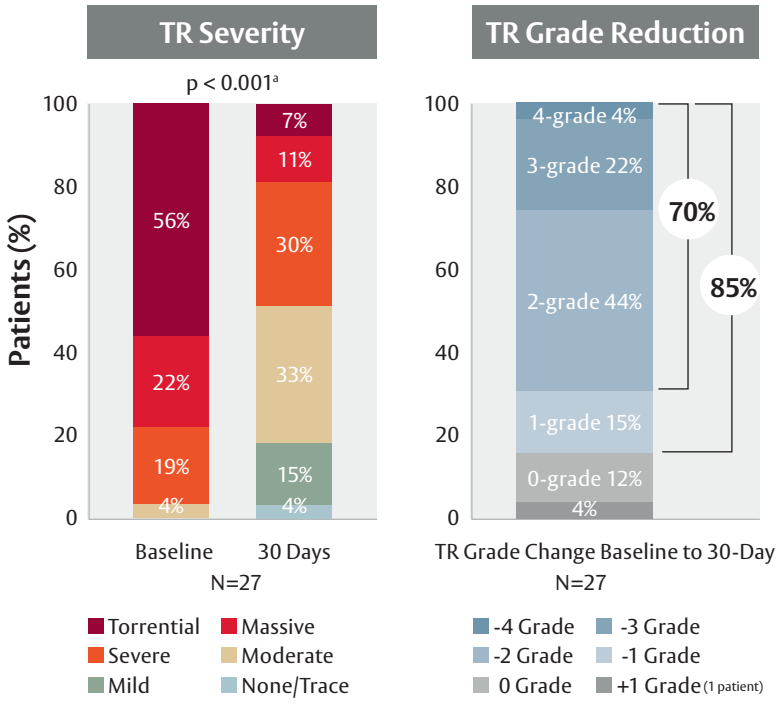
Clinically and statistically significant improvements at 30 days

- This initial experience of PASCAL transcatheter valve repair system early feasibility study showed a favourable safety profile and performed as intended in patients with symptomatic tricuspid regurgitation.
- Despite 55% torrential TR at baseline, importantly, 85% had at least 1 TR grade reduction and 70% patients had at least 2 TR grade reduction at 30 days.
- At 30 days, the major adverse event rate was low at 5.9% with no mortality, stroke, MI, or reintervention.
- Patients experienced significant improvements in functional status, quality of life, and exercise capacity.

Study design & baseline parameters[1]

Study Design: Multicenter, prospective, single-arm study		
Total patients: 34	Gender: 53% female	NYHA Class III/IV: 79%
Mean age: 76 years	TR severity ≥ severe (3+ grade): 97%	Atrial fibrillation/flutter: 88%

85% ≥1 and 70% ≥2 grade TR grade reduction



No mortality and 94.1% freedom from MAE* at 30-day

Safety Profile	%(n)
All-cause mortality	0
Cardiovascular mortality	0
Myocardial infarction	0
Stroke	0
Renal complications requiring dialysis or renal replacement therapy	0
New need for renal replacement therapy	0
Severe bleeding	5.9% (2)
Re-intervention related to device	0
Major access site and vascular complications requiring intervention	0

*MAE=major adverse events

N=34

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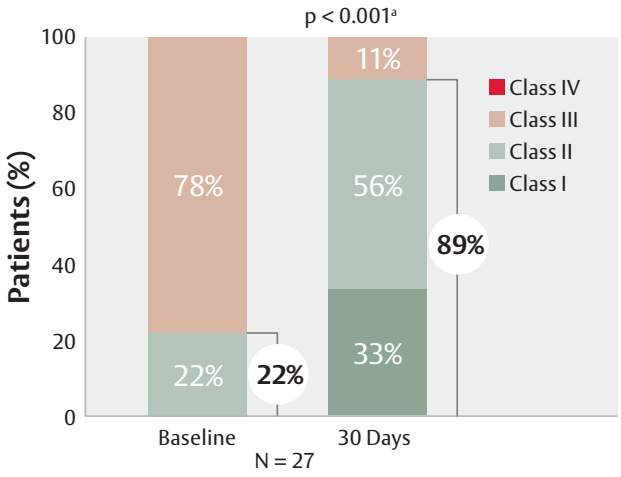
Procedural characteristics

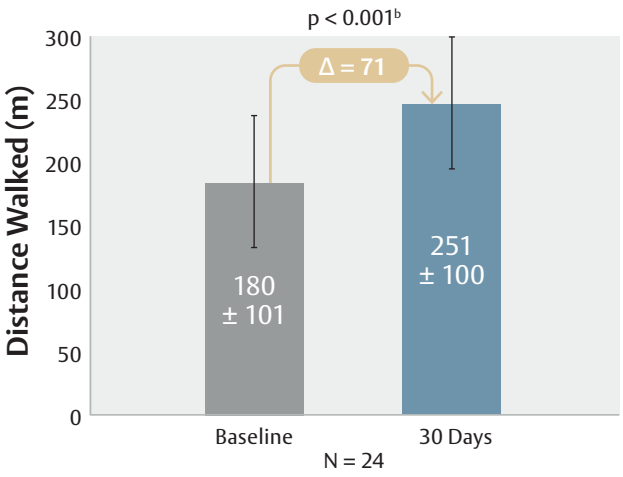
Implant success rate†: 85.3% (29/34)	†Implant is deployed as intended and the delivery system is successfully retrieved as intended at the time of the patient's exit from the cardiac catheterization laboratory.
Mean number of devices implanted: 1.2	Procedure time (skin-to-skin): 168 ± 152 min

Significant improvements in functional improvement and exercise capacity

NYHA Classification*

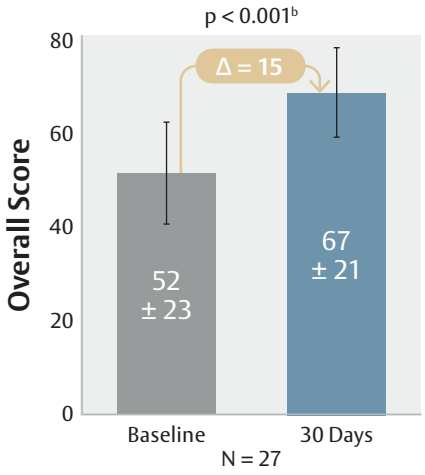


6 Minute Walk Distance



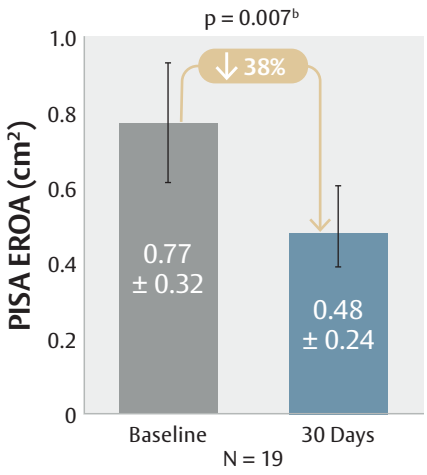
Significant improvement in quality of life

KCCQ Overall Score**

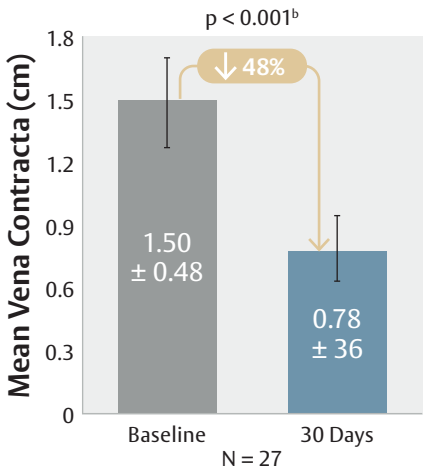


Significant decrease in key TR echo parameters

PISA EROA



Vena contracta



* New York Heart Association, Functional Classification (NYHA)

** Kansas City Cardiomyopathy Questionnaire (KCCQ)

[a] Wilcoxon Signed-Rank Test

[b] T-test; error bars represent 95% confidence intervals

[1] Kodali, S., et al. (2021). "Feasibility Study of the Transcatheter Valve Repair System for Severe Tricuspid Regurgitation." JACC 77(4): 345-356.

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