Early Outcomes of Real-World Transcatheter Tricuspid Valve Replacement

30-day results with the EVOQUE valve

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Study Design and Aim

Investigator-initiated, retrospective analysis designed to evaluate the **safety and efficacy** of the EVOQUE system used commercially to treat **176 consecutive real-world** patients with at least severe TR in 12 European Heart Valve Centers. Efficacy and safety endpoints were defined according to TVARC criteria as Clinical success and evaluated at 30 days†.

Patient Baseline Characteristics	
176 elderly patients	78 years old median age
	72% female
	80% in NYHA III/IV
	54% median LVEF
	51% TRI-SCORE ≥6 points
72% with massive or torrential TR	28% severe TR
	36% massive TR
	36% torrential TR
Predominantly secondary TR	15% primary TR
	46% secondary atrial TR
	29% secondary ventricular TR
	10% CIED-related TR
Frequent comorbidities	89% atrial fibrillation
	69% chronic kidney disease stage ≥3
	48% previous HFH within the past 12 months
Real-world patients, different from trial experience[2-3]	21% moderate/severe RV dysfunction
	59% RV dilatation
	46% pulmonary hypertension
	8% prior surgical or transcatheter TV interventions
CIED leads and conduction abnormalities	37% CIED lead crossing the TV
	32% preexisting conduction disturbances in patients without PM

Procedural success, safety & effectiveness

High intraprocedural success rate: 97%

Reduced device time[2]: 45 min
Average procedure duration: 103 min

Low rate of procedural complications:
- 0.6% device malposition (n=1): embolization into RV
- 0.6% in-hospital reintervention (n=1) for PVL closure
- 3.4% in-hospital mortality (n=6)
- 1.1% acute right HF requiring inotropic support (n=2)
- 4.5% periprocedural cardiac decompensation (n=8)

Successful TR resolution at discharge:
- 98% mild or less TR (TR ≤ 1+)
- 2% moderate or severe TR (TR ≥ 2+)

Successful TR resolution, with significant clinical and functional improvements at 30 days

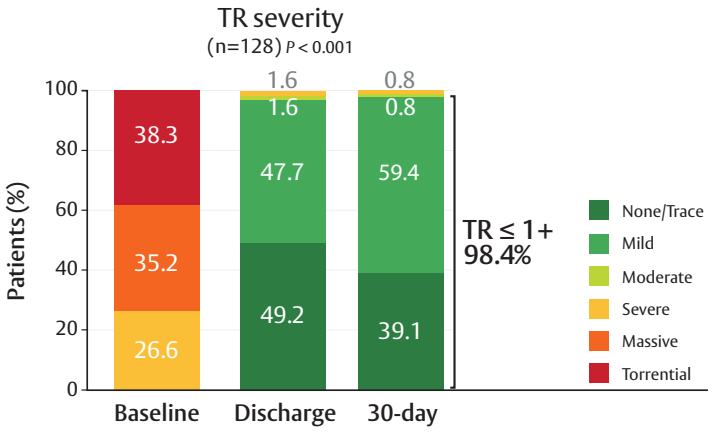


Figure 1: TR severity at baseline, discharge and 30-day follow-up (paired analysis).

High TVARC clinical success†: 87%

Significant HF symptoms improvement:
- 80% in NYHA class I/II vs 20% at baseline ($P < 0.001$)
- 71% improved by at least one NYHA class

Consistent TR resolution at 30 days:
- 98% with mild or less TR (Figure 1)

Significant improvements in clinical & functional outcomes:
- Reduced peripheral edema and body weight
- Improved renal and liver function

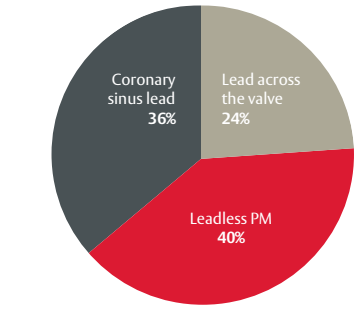
Safety outcomes at 30 days[‡]

All-cause death	5.1%
HF hospitalization	5.1%
Composite death or HF hospitalization	8.5%
Bleeding	9.7%
Major vascular complications	1.1%
Major valve thrombosis	1.7%
Reintervention	0.6%
Myocardial infarction	0.0%

Predictors of new PPM implantation & clinical outcomes

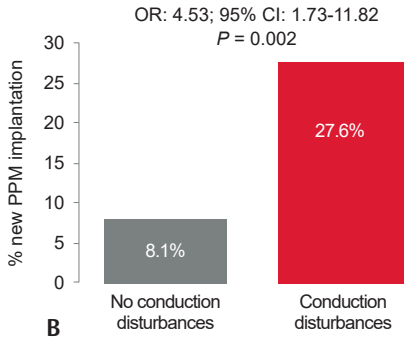
- **19% new PPM rate in pacemaker-naïve patients.** A leadless PM was the preferred pacing strategy (Figure 2A). 84% of PPM implantations occurred within the first week.
- **Predictors of PPM implantation:** Patients with preexisting conduction disturbances were 4 times more likely to require PPM implantation (Figure 2B).
- **Predictor of clinical failure:** Patients with baseline moderate or severe RV dysfunction had a 3-fold increased risk of clinical failure at 30 days (Figure 2C).
- **Predictors of functional improvement:** Patients with massive or torrential TR were more likely to improve in NYHA class by at least one grade.

Type of new PPM implantation



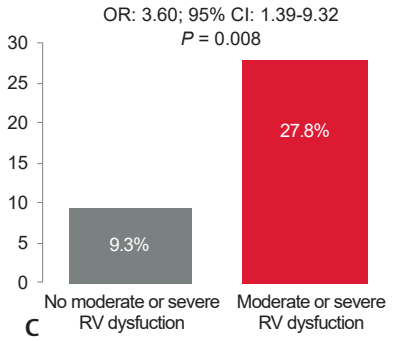
A

Predictors of PPM implantation



B

Predictors of clinical failure



C

Figure 2: A) Type of PPM device. B) Preexisting conduction disturbances are predictors of PPM implantation. C) Baseline moderate or severe RV dysfunction is predictor of clinical failure[§].

Summary of key findings[1]

- High rates of TVARC clinical success through 30 days, with 98% of patients achieving consistent TR resolution to mild or less.
- TR resolution was associated with excellent **clinical improvements** in terms of NYHA functional class, signs of right HF and hepatorenal congestion. Patients with **massive or torrential TR** were **more likely to experience functional improvement**.
- **Lower rates of complications** than previously described[2,3], with 19% new PPM implantation rate in pacemaker-naïve patients.
- Preexisting conduction disturbances were associated with increased risk of pacemaker implantation, while baseline RV dysfunction is a strong predictor of adverse clinical outcomes at 30 days.

Conclusion[1]

- This **first real-world analysis** of commercial use of the EVOQUE system demonstrated **high clinical success** rate, **significant improvements** in HF symptoms and hepatorenal function at 30 days, alongside a **lower incidence of complications** compared to earlier studies[2,3].

[†]Clinical success (TVARC definition): Proper device position with adequate performance (TR reduction ≤ moderate, TV mean gradient <5 mmHg) and absence of the following events: mortality, stroke, unplanned reintervention, life-threatening bleeding, major vascular or cardiac complications, stage 2 or 3 AKI, myocardial infarction, major valve thrombosis. [§]Clinical failure was defined as the absence of clinical success at 30 days. [‡]Selection of safety outcomes parameters at 30 days follow-up. For the full list, please refer to Table 6 of the manuscript[1].
CIED, cardiac implantable electronic devices; *HF*, heart failure; *HFH*, HF hospitalization, *NYHA*, New York Heart Association; *TR*, tricuspid regurgitation; *TV*, tricuspid valve; *TVARC*, Tricuspid Valve Academic Research Consortium; *AKI*, acute kidney injury; *PPM*, permanent pacemaker; *PM*, pacemaker; *TTVR*, transcatheter tricuspid valve replacement; *LVEF*: left ventricular ejection fraction; *RV*, right ventricular; *PVL*, paravalvular leak.

References
1. Angellotti D. et al., JACC Cardiovasc Interv. 2025. Online ahead of print. doi: 10.1016/j.jcin.2025.06.002.
2. Hahn R.T et al., N Engl J Med. 2025;392(2):115-126.
3. Kodali S. et al., JACC Cardiovasc Interv 2022;15:471-480.

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