

Clinical Insights

SUMMARY OF CLINICAL DATA

MITRACLIP® TRANSCATHETER MITRAL VALVE REPAIR

REAL WORLD USE OF MITRACLIP THERAPY IN US – RESULTS FROM THE STS/ACC TVT REGISTRY



PERSPECTIVE

First published 1-year report from the STS/ACC TVT Registry on real world use of the MitraClip® System (Abbott, Menlo Park) in U.S. patients following FDA approval in 2013.¹ Demonstration of safety and effectiveness in commercial use is important to strengthen MitraClip therapy as the pioneer in transcatheter mitral valve repair.

HIGHLIGHTS

- **MitraClip therapy in real world use is safe and achieved meaningful mitral regurgitation (MR) reduction** ($\leq 2+$) in elderly and highly comorbid DMR patients who are unsuited for surgery.
- These real world results from the STS/ACC TVT registry are **consistent with earlier MitraClip studies, and affirm improved patient survival with reduced need for mitral valve interventions through 1-year** when severe MR is alleviated.²
- **Long-term patient outcomes** following MitraClip treatment can be monitored from the CMS claims database via links to the STS/ACC TVT registry.

WHAT IS THE STS/ACC TVT REGISTRY?

The Transcatheter Valve Therapy (TVT) registry is a joint initiative of the Society of Thoracic Surgery (STS) and American College of Cardiology (ACC) to create a national database of transcatheter valve replacement and repair procedures at participating US centers to:

- Perform post-market surveillance safety and outcomes
- Create benchmarks for hospital practices of such procedures
- Enable scientific research and publication of the registry data
- Satisfy requirements for CMS national coverage

Source: <https://www.ncdr.com/webncdr/tvt/publicpage/home>

STUDY DESIGN AND METHODS¹

- 2,952 MitraClip patients from 145 hospitals who enrolled into the TVT registry from November 2013 to September 2015.
- Patients were predominantly symptomatic, primary degenerative MR (DMR) grade $\geq 3+$, and STS-PROM $\geq 6\%$ (MV repair) or $\geq 8\%$ (MV replacement). All were deemed unsuitable for surgery by a site heart team.
- Baseline, procedural, and in-hospital results came from the Registry. Post-discharge outcomes for a subgroup of 1,867 patients came from links to the CMS national claims database.
- All site reported strokes, cardiac surgeries, and valve events were adjudicated by a board certified cardiologist from the Duke Clinical Research Institute.

COHORT BASELINE CHARACTERISTICS

This was an elderly cohort deemed unsuited for surgery, and highly comorbid with history of ischemia and atrial fibrillation, compromised LVEF, and documented mitral leaflet prolapse or flail in most patients.

- Median age of 82 years
- STS-PROM of 6.1% (repair) or 9.2% (replacement)
- 93.0% had Grade ± 3 or 4+ MR
- 85.9% had only degenerative MR, 8.6% had only functional MR, 8.9% had both
- 85% were at NYHA class III/IV prior to treatment
- 50.3% were deemed frail

PROCEDURAL RESULTS

- High acute procedural success of 91.8%.³
 - 82.8% of cases involved the A2-P2 segments
 - 34.5% received multiple Clips
 - 1.5% site-reported single-leaflet device attachment (SLDA) rate
- Majority were discharged directly to home (85.9%).
- Short median hospital stay of 2.0 days.

EFFECTIVENESS OUTCOMES

- 92.0% of patients had their MR reduced to $\leq 2+$, increased from 86% in earlier trials.²
- Importantly, successful MR reduction (2+ or less) significantly improved patient prognosis [FIGURE 1]:
 - Lower in-hospital and 1-year mortality
 - Lower SLDA rate
 - Shorter hospital stay
 - Less need for reintervention with mitral valve surgery or MitraClip therapy
- Contrarily, less successful procedures led to poorer outcomes.
 - Much higher in-hospital mortality and doubling of 1-year death rates

SAFETY

- Low mortality, myocardial infarction, and stroke rates through 1-year [TABLE 1].
- Infrequent MV reinterventions. When needed, MitraClip therapy was used more often than surgery.
- Mortality and heart failure (HF) rehospitalization at 1-year were 25.8% and 20.2%, consistent with the EVEREST II/REALISM High Risk Cohort (22.8% and 19.8%).³
- Not unexpectedly in an elderly comorbid population, persistent risk of death was associated with age, residual MR, dialysis, lung disease, baseline LVEF, and severe tricuspid regurgitation (TR), which are also factors related to poor outcomes after mitral valve surgery [FIGURE 2].

RESULTS BY MR ETIOLOGY

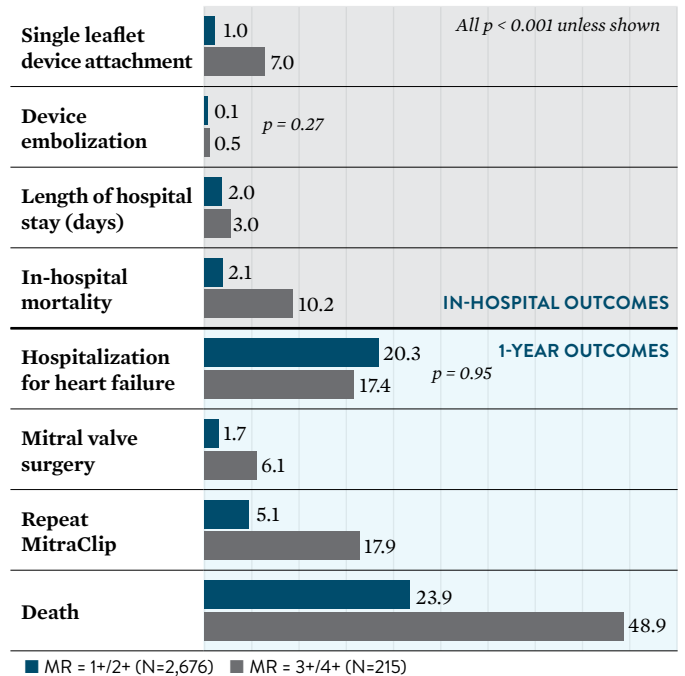
- MitraClip therapy was deemed by physicians to be suitable in some FMR patients from the CMS cohort (297/1,867).
- Given the small patient sample, no conclusions can currently be made regarding MitraClip therapy for FMR vs. DMR despite the higher 1-year mortality (31.2% versus 24.7%) and HF rehospitalization (32.6% versus 20.5%) rates reported.
- That answer lies in the COAPT RCT results expected in late 2018, which compares MitraClip therapy + optimal medical therapy to optimal medical therapy alone for HF patients with FMR.

CONCLUSIONS

- In the U.S., commercial transcatheter mitral valve repair with **MitraClip therapy demonstrates high procedural success (91.8%) with low incidences of in-hospital mortality (2.7%) and mitral valve surgery (0.7%)** for severely symptomatic MR patients with prohibitive surgical risk.
- Patient factors influencing long-term outcomes include age, LVEF, FMR, severe tricuspid regurgitation, moderate or severe lung disease, and post-procedural residual MR.

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FIGURE 1. OUTCOMES ACCORDING TO POST-IMPLANT MITRAL REGURGITATION



Patients who required conversion to open cardiac surgery (n = 20) are included in the patients with grade 3 or 4 post-implant MR.

Unless specified, all values are in %.

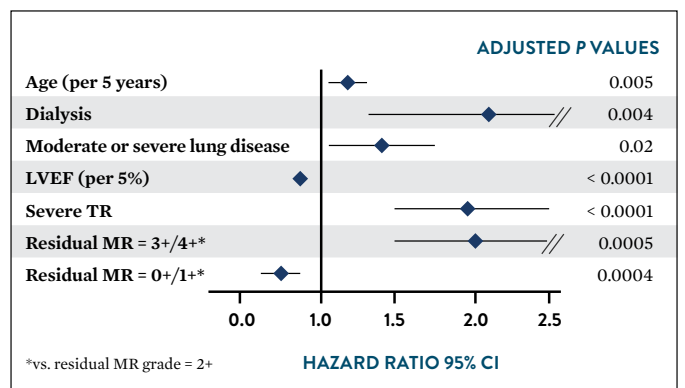
Adapted from Sorajja et al. *J Am Coll Cardiol.* 2017;70(19):2315-2327.

TABLE 1. CLINICAL OUTCOMES: IN-HOSPITAL, 30-DAY, AND 1-YEAR

PARAMETER, %	IN-HOSPITAL	30 DAYS	1 YEAR
Death	2.7	5.2	25.8
Myocardial infarction	0.1	0.2	2.5
Stroke			
Any stroke	0.4	1.0	2.7
Hemorrhagic	0.03	0.4	0.6
Heart failure hospitalization	-	4.7	20.2
Mitral valve surgery	-	0.4	2.1
Repeat MitraClip	-	1.3	6.2

Adapted from Sorajja et al. *J Am Coll Cardiol.* 2017;70(19):2315-2327.

FIGURE 2: MULTIVARIATE PREDICTORS OF 1-YEAR MORTALITY*



1. Sorajja P et. al., Outcomes with Transcatheter Mitral Valve Repair in the United States: An STS/ACC TVT Registry Report. JACC 2017; 70 (19):2315-2327
2. Glower DD et al. Percutaneous Mitral Valve Repair for Mitral Regurgitation in High-Risk Patients. Results of EVEREST II study. JACC 2014; 64:172-81
3. Acute procedure success defined as acute reduction in MR to grade 2 or less, without conversion to cardiac surgery and without in-hospital mortality

Caution: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use provided inside the product carton (when available), at eifu.abbottvascular.com or at Manuals.sjm.com for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

Photos on file at Abbott.

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