

# Percutaneous Mitral Valve Repair With the MitraClip System for Severe Mitral Regurgitation in Patients With Surgical Mitral Valve Repair Failure



**To the Editor:** Surgical mitral valve repair (SMVR) is the preferred intervention for patients with either symptomatic severe mitral regurgitation (MR) or asymptomatic severe MR and left ventricular dysfunction (1). The rate of freedom from severe MR 10 years after SMVR, however, is reported to be 70% (2), leading to a

considerable number of mitral valve reinterventions, which carry substantial risk, particularly in elderly patients and in those with significant comorbidities.

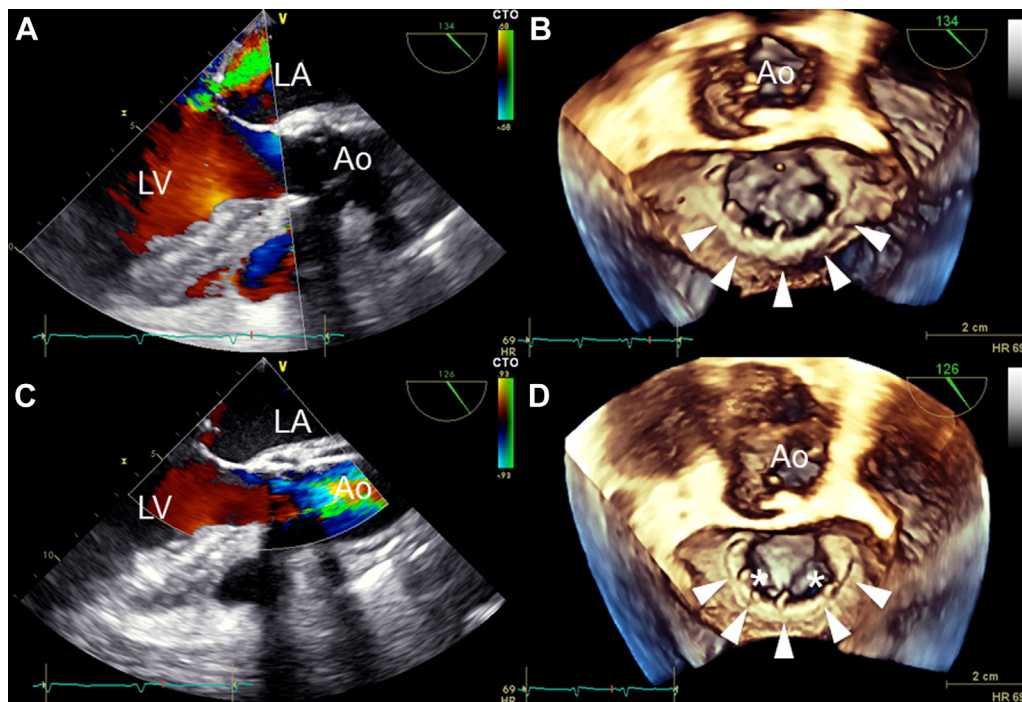
Percutaneous mitral valve repair (PMVR) with the MitraClip system (Abbott Laboratories, Abbott Park, Illinois) recently emerged as a promising therapeutic alternative to SMVR in patients who are at high risk or are unsuitable for conventional surgery (3). Because of its reduced invasiveness compared with conventional surgery, PMVR could as well function as a potential alternative to reoperation in patients with SMVR failure. Although the feasibility of transcatheter valve implantation after SMVR failure has already been reported (4), studies assessing the feasibility and efficacy of PMVR with the MitraClip system in this setting are very limited (5). We report, therefore, our initial experience with MitraClip implantation in patients with SMVR (i.e., annuloplasty) failure.

Between August 2008 and June 2013, a total of 154 consecutive patients with moderate to severe (grade 3+) or severe (grade 4+) MR determined to be at high surgical risk who underwent PMVR at our institution were prospectively included in our GRASP

**Table 1** Patient Characteristics, Procedural Details, and Follow-Up Data

Variable	Patient #1	Patient #2	Patient #3	Patient #4	Patient #5	Patient #6
Age (yrs)	74	77	79	75	72	72
Sex	Female	Female	Female	Male	Male	Female
NYHA functional class (baseline)	3	3	3	4	2	4
Logistic EuroSCORE (%)	42.9	12.9	13.6	13.0	15.0	20.1
STS score (%)	11.4	4.2	6.0	4.6	5.0	6.0
Interval between SMVR and PMVR	12 yrs	6.5 yrs	5 yrs	10 yrs	8 yrs	7 days
Type of surgical ring	Carpentier-Edwards	Sovering Miniband	Carpentier-Edwards	Carpentier-Edwards	Sovering Miniband	Cosgrove-Edwards
<b>Pre-procedural</b>						
Rhythm	SR	SR	SR	AF	AF	SR
LVEF (%)	30	30	35	35	29	45
MR etiology	Functional	Functional	Functional	Functional	Functional	Functional
Tethering (involved leaflet)	Yes (P)	Yes (P)	Yes (P)	Yes (P)	Yes (A, P)	Yes (A)
MR jets	Central	Central	Central-medial	Central-medial	Central	Central-lateral
MR grade	3	3	3	4	4	4
Systolic PAP (mm Hg)	50	50	35	45	35	60
Mean pressure gradient (mm Hg)	1.8	2.5	2.7	4.5	2.6	3.8
Mitral valve area (cm <sup>2</sup> )	4.3	3.3	3.0	3.7	3.7	3.7
Coaptation depth (mm)	9	8	8	10	8	5
Coaptation length (mm)	5	6	4	5	4	3
<b>Procedural details</b>						
Device success	Yes	Yes	Yes	Yes	Yes	Yes
Number of clips needed	1	1	1	1	1	1
Device implantation time (min)	55	33	67	60	75	30
Total fluoroscopy time (min)	27	13	33	28	35	18
<b>Post-procedural</b>						
MR grade	1	1	1	2	1	1
Mean pressure gradient (mm Hg)	5	3.1	5	6	4.8	5
Mitral valve area (cm <sup>2</sup> )	2.6	1.9	2.5	1.5	2.4	1.9
Procedural complications	None	None	None	None	None	None
Hospital stay (days)	4	5	2	5	2	NA
<b>Follow-up</b>						
Follow-up (months)	31	12	12	6	3	NA
MR grade	1	1	3	1	1	NA
LVEF improvement	Yes	Yes	No	Yes	Yes	NA
NYHA functional class	2	2	3	2	1	NA

A = anterior leaflet; AF = atrial fibrillation; EuroSCORE = European System for Cardiac Operative Risk Evaluation; LVEF = left ventricular ejection fraction; MR = mitral regurgitation; NA = not available; NYHA = New York Heart Association; P = posterior leaflet; PAP = pulmonary artery pressure; PMVR = percutaneous mitral valve repair; SMVR = surgical mitral valve repair; SR = sinus rhythm; STS = Society of Thoracic Surgeons.



**Figure 1** Transeophageal Echocardiography Before and After the Procedure From a Representative Case (Patient #6)

In the long-axis view, mitral regurgitation reduction from severe (A) to trivial (C) is shown, whereas in the 3-dimensional echocardiographic view from the left atrium (LA), the annuloplasty ring (Cosgrove-Edwards; white arrowheads) is clearly demonstrated in the posterior annulus (B,D) with a double orifice (white asterisk) after MitraClip implantation (D). Ao = aorta; LV = left ventricle.

(Getting Reduction of Mitral Insufficiency by Percutaneous Clip Implantation) registry (6). The decision to proceed with PMVR was discussed by a dedicated heart team, including experienced clinical and interventional cardiologists, cardiovascular surgeons, and anesthesiologists. Qualifying inclusion and exclusion criteria for PMVR, as well as details of the procedure, were previously reported (3). Throughout the study period, PMVR was performed in 6 patients (3.9%) with surgical mitral valve annuloplasty failure. Baseline, procedural, and follow-up characteristics are listed in Table 1. The median interval between SMVR and PMVR was 8 years (range: 5 to 12 years). One case was performed, however, 7 days after SMVR as a “bailout” procedure for acute surgical failure. Device success, defined as residual MR grade  $\leq 2+$  after clip implantation, was achieved in all patients. Post-procedural MR grade, the mean pressure gradient of the mitral valve ( $4.9 \pm 0.9$  mm Hg), and mitral valve area ( $2.1 \pm 0.4$  cm<sup>2</sup>) were satisfactory. No cases of procedural death, stroke, myocardial infarction, or urgent cardiovascular surgery occurred. Patient # 6, in whom PMVR was performed in the acute phase (i.e., 7 days after SMVR), died because of multiple-organ failure during the hospital stay, thus imparting all-cause and cardiovascular mortality rates of 16.7% and 0%, respectively. Follow-up was available in all remaining 5 patients (median follow-up period 12 months; range: 3 to 31 months). All patients but one (Patient #3) experienced improvements in New York Heart Association (NYHA) functional class compared with baseline and maintenance or improvement of MR status compared with post-procedural at follow-up (Table 1).

When our findings are put into perspective with the overall population from the GRASP registry, the mean age and logistic European System for Cardiac Operative Risk Evaluation score were significantly higher in patients with versus without prior SMVR ( $74.8 \pm 2.8$  years vs.  $71.6 \pm 10.2$  years,  $p = 0.041$ , and  $19.6 \pm 11.7$  years vs.  $10.4 \pm 10.9$  years,  $p = 0.046$ , respectively), whereas no significant differences were observed in terms of baseline NYHA functional class and left ventricular ejection fraction ( $37.0 \pm 7.3\%$  vs.  $36.8 \pm 13.2\%$ ,  $p = 0.942$ ). All patients with prior SMVR underwent successful procedures with the implantation of only 1 clip, which was significantly lower compared with those without prior SMVR ( $p = 0.027$ ). No significant differences were documented regarding device implantation and total fluoroscopy time, as well as length of hospital stay between the groups.

Patients with prior surgical mitral valve annuloplasty have reduced mitral valve areas due to the previously implanted annuloplasty ring; therefore, being able to effectively reduce MR by implanting only 1 clip (representative images shown in Fig. 1) per patient in our series was noteworthy, as we could show the effectiveness of the intervention while minimizing concerns regarding potential secondary increases in pressure gradients. Indeed, acceptable post-procedural transvalvular mean pressure gradients and mitral valve areas were demonstrated in all patients (Table 1). Furthermore, we were able to demonstrate the stability of MR reduction coupled with improvement in left ventricular ejection fraction and NYHA functional class in all but in 1 patient over time. Another important finding, despite our small number of patients, was the safety of PMVR in patients with SMVR failure;

in fact, notwithstanding the high baseline patient risk profile, no procedure-related adverse events were documented.

We acknowledge some limitations of our pivotal study. First, the comparisons between patients with and without prior SMVR should be interpreted with caution, because they were not pre-defined in our initial protocol; nevertheless, they help in settling our patients' high-risk clinical status while reassuring the feasibility and original signs of effectiveness of the intervention performed. Second, larger series and longer term follow-up are warranted to confirm our initial findings in this highly selected population. Finally, determining the most appropriate therapy (i.e., PMVR or surgical reoperation) for patients with SMVR failure warrants future investigation.

In conclusion, we were able to demonstrate in a preliminary experience the safety and efficacy of PMVR with the MitraClip therapy in patients with surgical mitral valve annuloplasty failure. The promising results demonstrated herewith, therefore, open a new avenue for further investigation of the role of MitraClip implantation in this complex clinical scenario.

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## Letter to the Editor

## Endpoints for Diuresis

## Are We There Yet?



Diuretics and relief of congestion remain the mainstay of therapy in patients hospitalized with heart failure (HF), regardless of ejection fraction. However, limited data and established practice guidelines are available to guide clinicians in the duration and intensity of inpatient diuresis. In a recent issue of the *Journal*, van der Meer et al. (1) add to the growing body of published data indicating that changes in certain parameters during hospital stay, including renal function (2), body weight (3), and intravascular volume (4), might predict post-discharge clinical course. In addition to defining the ideal surrogate marker(s) to reflect clinical euvoemia, future initiatives in this area should address the optimal method of decongestion and the compartment of desired fluid removal (intravascular, extravascular, and so forth). Subpopulations such as patients with chronic kidney disease, advanced HF, predominant right-sided HF, and HF with preserved ejection fraction likely warrant special consideration. Matching the right marker of decongestion with the right patient population will be an important objective of future studies.

Overall length of stay in HF has trended down, despite persistently high rates of post-discharge outcomes (5). This might reflect inadequate congestion, because approximately 50% of HF patients lose <2 kg during hospital stay (6). Early readmissions might be related to hemodynamic perturbations rather than progression of HF and thus might be at least partially responsive to aggressive volume management. Comparative strategies for various metric-guided approaches to decongestion should be prospectively assessed to optimize post-discharge outcomes in HF. The tremendous economic and clinical burden of HF demands a more nuanced, systematic, and standardized approach to the management of congestion.

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