



## Research Brief

# Percutaneous edge-to-edge mitral valve repair for symptomatic high surgical risk patients with significant mitral regurgitation – Short term and one year follow up results from a single center in India

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## ABSTRACT

This series reports the safety and feasibility of MitraClip (Abbott Vascular) in 7 high surgical risk Indian patients with symptomatic mitral regurgitation (MR). The clip was deployed successfully in all patients, and more than one clip was required in 5. All had reduction in MR to  $\leq 2+$ . Mean mitral valve gradient was  $3.0 \pm 0.8$  mmHg. At 12 months follow up, all were alive, and the MR grade was 1+ in 6 patients and 2+ in one. Mean MV gradient was  $3.4 \pm 1.0$  mmHg. The modified Kansas City Quality of life (KCQ) analysis revealed significant improvement in their quality of life ( $p < 0.0001$ ).

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## 1. Introduction

Mitral regurgitation (MR) is the most common valvular heart disease among the adults aged more than 55 years.<sup>1</sup> It results either from the abnormality of the valve apparatus (primary MR, P-MR) or from left ventricular (LV) dysfunction and alterations in LV geometry (secondary MR, S-MR).<sup>2</sup> Severe MR causes progressive LV dilatation, dysfunction, heart failure and increased mortality.<sup>3</sup> Surgical repair or replacement is the gold standard for treatment, however, it is not always feasible in a significant proportion of patients.<sup>4</sup> Trans-catheter edge to edge repair with MitraClip system (Abbott Vascular, Menlo Park, California, US) is less invasive therapy that approximates the mitral leaflets and decreases MR similar to the surgical Alfieri stitch.<sup>5</sup> The present case series evaluated the feasibility and safety of percutaneous edge to edge repair with

MitraClip in high surgical risk symptomatic Indian patients with significant MR.

## 2. Methods

The study comprised of 7 high surgical risk symptomatic patients with severe P or S-MR. The following echocardiographic criteria were used for patient selection: In P-MR, the eligibility criteria were flail gap  $< 10$  mm and width  $< 15$  mm and in S-MR, the coaptation depth of  $< 10$  mm and coaptation length of  $> 2$  mm.<sup>6</sup> The demographic, clinical, and echocardiographic data were captured retrospectively from the case records, while procedural and TEE data were collected prospectively. They were followed with echocardiography at 1 month, and 6 months. 12 month evaluation was done by their local physician due to travel restriction from lockdown from COVID-19 pandemic. However, their clinical status was assessed via phone conversation using modified Kansas City questionnaire (KCQ) on Quality of Life (QoL).<sup>7</sup>

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### 3. Results

The mean age of the population was  $76.7 \pm 7.1$  years and 4 were males. The mean EuroScore II and STS score predicted mortality were  $7.4 \pm 4.3$  % and  $7.2 \pm 5.2$  % respectively. The MR was P-MR in 5 and S-MR in 2 patients. Of the 5 patients with P-MR, the pathology involved P2 segment in 3, A2 in one and A3 in the other patient. The MR was grade 4+ in 6 and grade 3+ in 1 patient. The mean effective regurgitation orifice area and regurgitation volume were  $0.5 \pm 0.3$  cm<sup>2</sup> and  $78.9 \pm 56.0$  ml respectively. The mean left ventricular end diastolic diameter (LVEDD), left ventricular end systolic diameter (LVESD), left ventricular end diastolic volume (LVEDV), left ventricular end systolic volume (LVESV), and left ventricular ejection fraction (LVEF) were  $54.5 \pm 5.1$  mm,  $33.3 \pm 5.3$  mm,  $158 \pm 45.6$  ml,  $73.3 \pm 2$  ml, and  $53.9 \pm 12.5$  % respectively. The mean right ventricular systolic pressure (RVSP) was  $70.7 \pm 23.2$  mmHg (Supplementary table 1). The clip was deployed successfully in all patients and more than one clip was required in 5 patients (Supplementary figure 1 and 2). The mean left atrial pressure decreased from  $27.7 \pm 11.1$  mmHg to  $18.0 \pm 6.5$  mmHg and mean 'V' wave from  $57.4 \pm 23.5$  mmHg to  $24.5 \pm 13.1$  mmHg. The mean mitral valve gradient was  $3.4 \pm 1.0$  mmHg. All had reduction in MR to  $\leq 2+$ . The mean duration of the hospital stay was  $4.0 \pm 2.1$  days. One patient had small pericardial effusion at the time of discharge which required pericardiocentesis after 3 weeks (Supplementary table 2).

The mean duration of follow up was  $476 \pm 122$  days. All were in NYHA class I/II functional status. The QoL analysis performed using Radar plot test demonstrated significant improvement in QoL ( $p < 0.0001$ ), in both individual and aggregate analyses (Supplementary figure 3).

On 6 months follow up echocardiography, MR grade was 1+ in 6 patients and 2+ in one. The mean MV gradient was  $3.4 \pm 1.0$  mmHg. The mean LVEDD, LVESD, LVEDV, LVESV, LVEF and RVSP were  $52.8 \pm 3.6$  mm,  $34.3 \pm 4.1$  mm,  $109.7 \pm 28.4$  ml,  $52.8 \pm 19.7$  ml, and  $53 \pm 12.2$  % respectively (Supplementary table 3).

### 4. Discussion

Successful procedure with a reduction in the severity of MR to  $< 2+$ , is an important determinant of post-procedure clinical improvement. Studies reported that persistent MR of  $> 2+$  severity as an independent predictor of heart failure re-hospitalization, all-cause mortality and worsening severity of MR following MitraClip therapy.<sup>8–11</sup> All patients in the current study had excellent reduction in MR severity and none had  $> 2+$  residual MR. MitraClip treatment results in decrease in MR severity leading to reduction in LA pressure (LAP) and V wave. Each 5 mmHg decrease in V wave was associated with a 49% improvement in 6 min walk test (MWT).<sup>12</sup> MitraClip reduces the effective mitral valve area and increases the trans-mitral gradients.<sup>13</sup> All patients in this study attained good reduction in mean LAP and V wave post procedure and none had mean trans-valvular gradient  $> 4$  mmHg. Although we did not get 6 MWT, the KCQ analysis demonstrated significant improvement in their QoL.<sup>7</sup>

Optimal MR reduction results in favorable LV remodeling, in the EVEREST II study, there was a significant reduction in the LVEDV, LVEDD, LVESV, and EF at 12 months follow up.<sup>6</sup> All patients in the current study also demonstrated significant reduction in LVEDD, LVEDV, and LVESV at 6 month follow up and all were in NYHA class I/II during follow up. This demonstrates favorable translation of acute procedural outcomes and subsequent LV remodeling to good

clinical outcomes. Furthermore, there was no mortality in this series till to date.

MitraClip percutaneous therapy to treat P-MR and S-MR was introduced in India very recently, and the experience is limited to a very small number of procedures thus far. This is the first series with short term and 12 months follow up data in India. Our results show that current MitraClip system can be safely used in Indian patients with smaller body surface area to treat symptomatic MR in whom surgical risk is prohibitive.

### 5. Conclusion

In selected symptomatic, high surgical risk Indian patients with significant MR, percutaneous edge-to-edge MV repair with MitraClip is feasible and safe. It is associated with improvement in functional status and favorable LV remodeling.

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### Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ihj.2021.05.003>.

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