

Real-world utilisation and outcomes of transcatheter mitral valve leaflet repair (TMVLR) in Asian patients with mitral regurgitation: A Singapore experience

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BACKGROUND

- Limited treatment options are available for patients with grade 3 or 4 (moderate-to-severe or severe) mitral regurgitation (MR) who are ineligible for surgery.
- Transcatheter mitral valve leaflet repair (TMVLR) is a minimally invasive procedure that aims to treat MR using an edge-to-edge leaflet clip device percutaneously inserted through a catheter.
- TMVLR appeared to be safe, with significantly lower all-cause mortality compared with medical treatment.
- The Ministry of Health's Medical Technology Advisory Committee (MTAC) recommended subsidy for TMVLR in treating patients with symptomatic grade 3 or 4 MR and ineligible for surgery, with effect from 30 June 2021.
- This is the first study in Singapore to assess the utilisation and outcomes of TMVLR procedures post-subsidy implementation in the real-world setting.

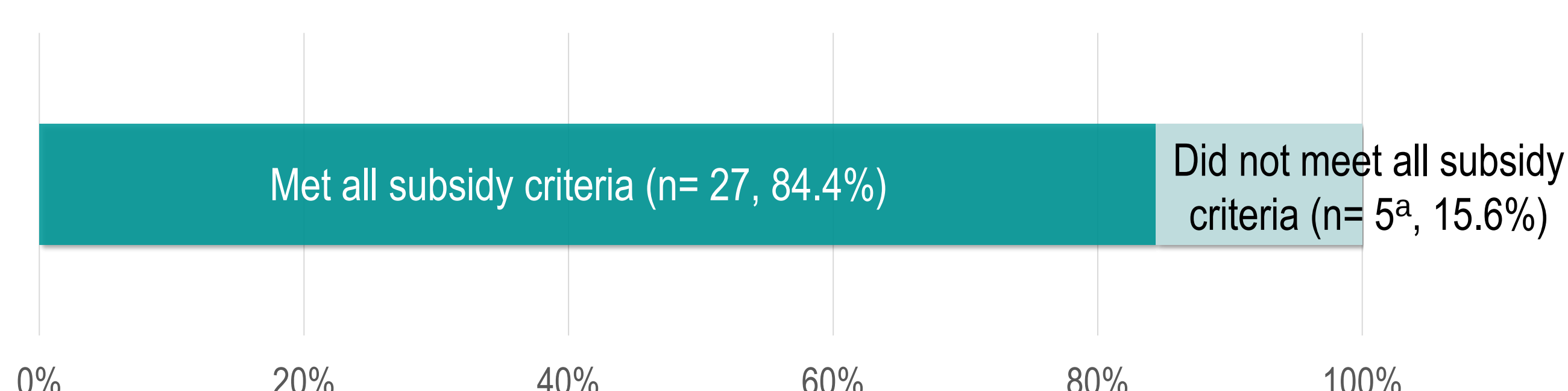
METHODS

- A prospective observational study was conducted using data submitted by public healthcare institutions from 30 June 2021 to 31 December 2022.
- Utilisation volume, patient characteristics and outcomes from all specialty heart centres in the public sector were collected.
- Adherence to the MTAC's recommended subsidy criteria was also assessed.
- Descriptive statistics was used for the analysis. Paired t-test was used to compare patients' degree of MR pre- vs. post-procedure.

RESULTS

- The number of patients who underwent TMVLR pre- and post-subsidy remained stable, with about 21 patients each year. In the 18 months post-subsidy period (30 June 2021 to 31 December 2022), 32 patients received TMVLR.
- TMVLR use was mostly in line with the subsidy criteria recommended by the MTAC (n = 27, 84%) (Figure 1), and all patients had high surgical risk as assessed by the multidisciplinary team.

Figure 1. Proportion of patients meeting the recommended subsidy criteria



^aAmong the 5 patients who did not meet all subsidy criteria, 4 patients did not meet the additional subsidy criteria of left ventricular ejection fraction (LVEF,%) for secondary MR, while 1 patient has not been treated with maximally tolerated medical therapy.

CONCLUSION

- Utilisation of TMVLR remained stable pre- vs. post-subsidy. TMVLR appeared to be effective in reducing MR degree with high procedural success. However, further monitoring is needed to better assess its longer-term safety and outcomes.
- Despite the small patient population, this study contributes to the limited real-world evidence on TMVLR in Asia.

Baseline characteristics

- The mean ($\pm$ standard deviation) age of patients who received TMVLR was 74.5 ± 10.2 years old, with around half of them being male (n= 18, 56%). Majority of the patients (n=22, 69%) had primary or degenerative MR.
- Most patients who received TMVLR were symptomatic with grade 4 (severe) MR and a high proportion had a history of congestive heart failure (Table 1).

Table 1. Baseline clinical characteristics and comorbidities of patients who underwent TMVLR from 30 June 2021 to 31 December 2022 (n= 32)

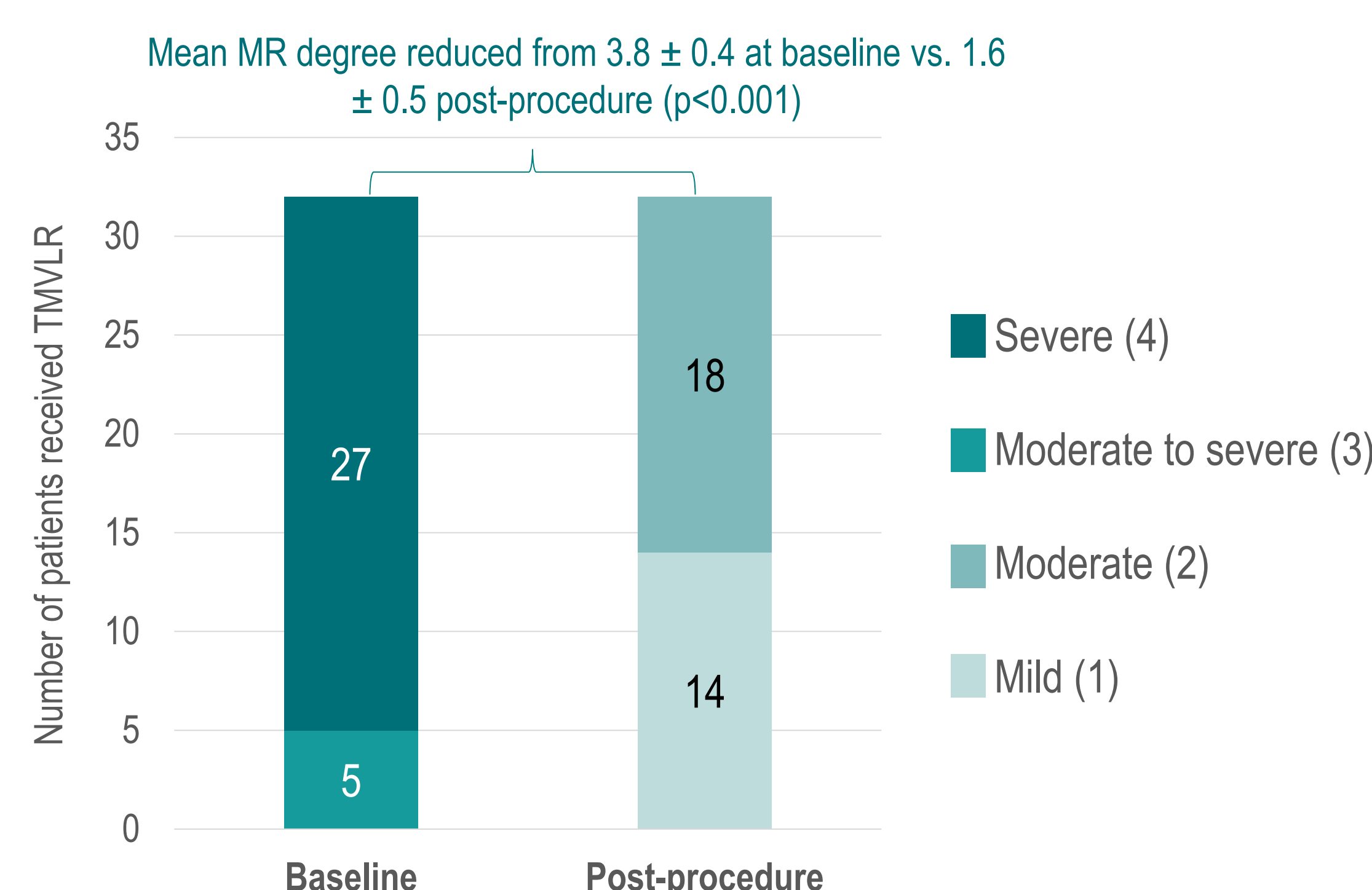
Characteristics		All TMVLR cases (n= 32)
Degree of MR, n (%)	Moderate to severe (3)	5 (15.6%)
	Severe (4)	27 (84.4%)
New York Heart Association (NYHA) class, n (%)	II	10 (31.2%)
	III	19 (59.4%)
	IV	3 (9.4%)
Left ventricular ejection fraction (LVEF), % (mean $\pm$ SD)		49.3 $\pm$ 18.9
History of congestive heart failure (CHF), n (%)		23 (71.9%)
History of atrial fibrillation (AF), n (%)		13 (40.6%)
Prior coronary artery bypass graft (CABG), n (%)		5 (15.6%)
Prior percutaneous coronary intervention (PCI), n (%)		9 (28.1%)

Abbreviations: MR: Mitral regurgitation; SD: Standard deviation

Post-procedural outcomes

- Most of the cases (n= 31, 97%) achieved procedural success^b with significant reduction in the degree of MR post-procedure (Figure 2).
- However, four of them (13%) experienced complications including pericardial effusion, atrial fibrillation and single-leaflet device attachment.
- At 30 days post-procedure, three patients (9%) were hospitalised due to CHF and two patients (6%) had cardiovascular-related deaths.

Figure 2. Patient's degree of MR at baseline vs. post-procedure



^bProcedural success is defined as successful clip implant with MR degree $\leq 2+$ post-procedure.