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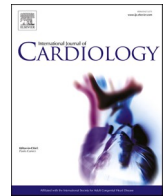
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Editorial

Transcatheter edge-to-edge repair of the mitral valve: A promising bridge to heart transplant for select patients?

Despite the advancements in pharmacological and device therapies, end-stage heart failure (HF) afflicts a significant proportion of HF patients and mortality rates remain considerably high [1]. Heart transplant remains the only curative therapy. Because of a limited pool of heart donors and consequently a steady but finite rate of heart transplant, there is a growing interest in alternative therapeutic options [2]. Left ventricular assist devices (LVADs) are performed as a bridge to transplantation or as a destination therapy. However, LVADs have several disadvantages, including cost and associated co-morbidities (e.g., driveline infection, bleeding, thromboembolic complications) [2].

Transcatheter Edge-to-Edge Repair (TEER) of the mitral valve has emerged as an alternative therapy for patients with moderate-severe and severe secondary mitral regurgitation (MR) in the setting of heart failure with reduced ejection fraction (HFrEF) and persistent symptoms refractory to maximally-tolerated medical therapy [3]. The 2020 American College of Cardiology/American Heart Association valvular heart disease guidelines provided a class IIa recommendation for TEER for patients with symptomatic cardiomyopathy and chronic severe secondary MR despite optimal guideline-directed medical therapy [4]. Concomitant severe MR is prevalent among patients with end-stage HF [5]. A prior analysis of the MitraBridge registry including 119 patients showed that TEER might be a feasible and safe bridge therapy in patients with moderate-severe and severe MR and end-stage HF. Notably, none of the patients died at 30-days. During a median of 532 days, 15% underwent elective transplant, 15% remained or could be included on the transplant list, and 23.5% had no further indications for transplant due to clinical improvement [6]. However, detailed data regarding the hemodynamic evaluation prior to and after TEER were lacking in that study.

It is in this context that the current investigation should be viewed. The investigators performed a retrospective observational analysis evaluating the hemodynamic parameters before and after TEER among patients with HFrEF and severe MR who otherwise could be considered for heart transplantation [7]. The study included 17 patients recruited between 2011 and 2019 and had repeat right heart catheterization (RHC) at a mean of 5.9 months. TEER was successful (i.e., post-procedure MR $\leq 2+$) in all patients, and the reduction of MR remained stable in 88% at follow-up. TEER was associated with a reduction in pulmonary vascular resistance (PVR) (3.5 ± 2.2 to 2.3 ± 1.2 wood units), systolic pulmonary artery pressure (55.4 ± 15 mmHg to 45.6 ± 9.8 mmHg), and transpulmonary gradient (12.0 ± 7.5 mmHg to 9.7 ± 5.3 mmHg). TEER was also associated with improved cardiac output (3.7 ± 0.9 l/min to 4.6 ± 1.3 l/min) and New York Heart Association (NYHA) functional class. In a subgroup of 5 patients with

elevated PVR > 3.5 , TEER was also associated with a significant reduction in PVR (6.1 at baseline to 2.9 wood units) and improvement in cardiac output (3.3 at baseline to 4.4 l/min). Collectively, these findings suggest that TEER might reduce PVR, which is known to be an important hemodynamic parameter in patients being evaluated for heart transplant and considered part of the eligibility criteria for heart transplantation. Similar to the analysis from the MitraBridge registry [6], the clinical outcomes of TEER in this study were reassuring. During a mean of ~ 36 months, 3 patients underwent heart transplant, 4 patients received LVAD, 1 patient was on the waiting list for heart transplant while 10 patients were managed with guideline-directed medical therapy. Survival rate was 86% at 1 year and 71% at 3 years [7].

The findings from this study are indeed provocative and relevant. The study suggests that TEER might reduce PVR and improve other hemodynamic parameters among select patients with end-stage HF. But some issues deserve further consideration. First, this is an observational study that lacks a control group. Second, the study was conducted in a single high-volume center. Hence, the findings might be subject to referral bias, which would limit the generalizability. Third, the timing of repeat RHC was not systematically planned, thus approximately half of eligible patients did not undergo repeat RHC and were not included in the analysis. Finally, the study spans over a long period (i.e., 8 years), and recruited only a small number of patients. Notwithstanding these issues, this study contributes to the literature supporting that TEER might be a feasible and safe procedure among select end-stage HF patients as a bridge to transplant.

TEER could be a potential “triage point” for patients with severe MR and end-stage HF who are otherwise potentially eligible for heart transplant, as a: bridge to transplant, bridge to candidacy for transplant in patients with potentially reversible contraindications, or medical management only if the symptoms improve after the procedure. However, a knowledge gap still exists on which subset of patients with severe MR and end-stage HF would benefit from TEER. In a secondary analysis of the Multicenter Study of MagLev Technology in Patients Undergoing Mechanical Circulatory Support Therapy with HeartMate 3 (MOMENTUM 3) trial including 927 patients who received LVAD, LVAD was associated with significant improvement in secondary MR within 1 month and this effect was sustained up to 2 years [8]. As such, patients who do not meet the criteria of the MOMENTUM 3 trial might be candidates for TEER. Noticeably, the patients in this study, as well as the MitraBridge registry, were relatively younger and had a higher prevalence of comorbidities including advanced renal disease [6,7], compared with those enrolled in the pivotal TEER trials [9,10]. This is an important consideration since some of these comorbidities are linked

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with worse outcomes after TEER. Incorporating a structural heart team approach would be reasonable in evaluating these patients to determine the appropriate therapeutic strategy.

The authors are to be commended on their efforts, which suggest that TEER may be a promising bridge that can improve the eligibility of select end-stage HF patients with severe MR for heart transplantation. The findings from this study should encourage future larger studies with an adequate control group before the widespread adoption of this approach.

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Declaration of Competing Interest

None.

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