



# Transcatheter edge-to-edge repair of the mitral valve in end stage renal disease patients: mortality fact check

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There exists a bidirectional relationship between chronic kidney disease (CKD) and cardiovascular diseases (1,2). Renal impairment is a well-established risk factor of poor outcomes in patients undergoing cardiovascular interventions, with the risk increasing as the degree of renal impairment worsens (3-5). Transcatheter edge-to-edge repair (TEER) [transcatheter mitral valve repair (TMVr)] with MitraClip (MC) has revolutionized the care of patients with symptomatic severe and moderate-severe mitral regurgitation (MR) who pose prohibitive surgical risk, resulting in widespread adoption since its approval (6,7). End-stage renal disease (ESRD) patients with significant MR are often not surgical candidates given their clinical and anatomic uniqueness (8). Considering the high morbidity and mortality burden associated inherently with ESRD, it was no surprise that this patient population were either excluded or underrepresented in the landmark trials evaluating the benefit of TMVr, despite the high prevalence of significant MR (6,7,9,10). Given their prohibitive surgical risk, TMVr could be a potentially viable option in this patient population as well. There is however, a significant paucity of data evaluating the outcomes of TMVr in patients with ESRD, both in the acute and long-term settings.

In a brief research report, Vindhya *et al.* using the United States Renal Data System (USRDS), evaluated the all-cause mortality outcomes and the readmission rates for ESRD

patients undergoing TMVr with the MC (11). The authors reported an in-hospital, 30-day, and 1-year mortality of 3%, 5%, 33.5%, respectively. While the in-hospital and 30-day mortality reported in this report is lower than reported in previous studies, the 1-year mortality rate is comparable to previously published data (8). In specific, Shah *et al.*, in their analysis of the National Cardiovascular Data Registry Transcatheter Valve Therapy registry, reported the in-hospital, 30-day and 1-year mortality among ESRD patients undergoing TMVr to be 6.5%, 13.5%, and 32.3%, respectively (8). Remarkably, the all-cause readmission rates in this study cohort were reported to be 25.7% and 78.4% at 30 days and 1 year, respectively. This is higher than the 30-day readmission rate previously reported by Sawalha *et al.* in a national readmission database analysis (12). Though the 1-year readmission rate is significantly higher compared to the report by Shah *et al.*, it is worth noting that the present study reported on all-cause readmission instead of heart failure-related readmissions (8). The findings conveyed by this research report present a unique opportunity to broaden our understanding of outcomes of MC implantation in this distinct patient population through real-world data. Importantly, it paves the path for further investigation of factors associated with morbidity and mortality in ESRD patients, with a prospect of improved care and patient optimization.

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Considering the above, the findings reported by Vindhya *et al.* should be considered with its merits and limitations (11). The study population was exclusively derived from a single registry based out of the United States. Differences in patient demographic profile, severity of competing comorbidities, patient optimization pre-procedurally, differences in operative technique across countries are some of the factors found to significantly affect mortality outcomes of TEER, irrespective of baseline renal function. As differences in patient profile can lead to significant variability in mortality outcomes, a true estimate of short- and long-term mortality rates is precluded by the lack of patient and procedural characteristics. This is supported by the findings of two landmark trials evaluating MC outcomes, the Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients with Functional Mitral Regurgitation (COAPT) and Percutaneous Repair with the MitraClip Device for Severe Functional/Secondary Mitral Regurgitation (MITRA-FR), wherein contrasting outcomes were secondary to differences in study population and patient selection criteria (6,7,13). This also emphasizes the impact of noncardiac comorbidities apart from renal disease on mortality and morbidity outcomes. In the present study, the authors have provided the prevalence of hypertension, atherosclerotic cardiovascular disease, heart failure, and diabetes mellitus. However, the prevalence of anemia in this study population was not reported. Anemia is an important risk factor of adverse outcomes, including late all-cause mortality after TEER, and ESRD patients are invariably anemic with a reported prevalence of >70% in literature (14). Anemia can increase the risk of cardiorenal syndrome in the postoperative period by increasing myocardial oxygen demand (15,16). Therefore, its prevalence in the study population should be carefully weighed in while evaluating mortality rates in ESRD patients undergoing TEER.

It is also important to recognize that the present study was limited by a small study population compared to registry-based studies that evaluated mortality rates in non-ESRD patients undergoing TEER. For instance, the study conducted by Khan *et al.* on patients from the National Inpatient Sample database, was used by the investigators to draw comparisons about in-hospital mortality rates between ESRD and non-ESRD patients undergoing TEER. It is worth noting that Khan *et al.* included 15,260 participants compared to the present study which only included 463 patients (17). Notably, the investigators from the present study report theirs to be the largest study

conducted till date in ESRD patients undergoing TEER. The authors attributed their findings of lower in-hospital and 30-day mortality rates to a larger study population in comparison to the small study conducted by Shah *et al.* in ESRD patients (8). However, Raheja *et al.*, in a similar and yet marginally larger study of 476 patients with ESRD, found an in-hospital mortality rate of 7.2% after MC which is remarkably higher than the 3% reported by Vindhya *et al.* (18).

Renal dysfunction of any severity, including ESRD, predisposes to a higher mortality rate in patients undergoing TEER compared to patients with intact renal function. However, the incidence of short- and long-term mortality cannot be accurately gauged in the absence of details of patient profile, especially other noncardiac comorbidities. Larger studies conducted across multiple centers, accounting for regional variations, are needed to understand the true incidence of both in-hospital, short-term, and long-term mortality after TEER. Careful patient selection, pre-procedural optimization, and postoperative care and follow-up are crucial to reduce mortality in this high-risk patient population.

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