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EDITORIAL COMMENT

# Anterior, Posterior, or Bileaflet Mitral Valve Pathology

## No Reason to Worry With M-TEER!

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Transcatheter mitral edge-to-edge repair (M-TEER) has evolved as safe and efficacious therapy for patients with significant mitral regurgitation (MR). In the early MitraClip (Abbott Cardiovascular) experience, patients deemed suitable for transcatheter repair with underlying degenerative (primary) MR (DMR) were highly selected. Patients with commissural pathologies, large prolapse or flail segments, calcifications in the clip landing zone, and small valve areas were often excluded.[1] As the therapy matured and the MitraClip device underwent several iterations, interventionalists step by step expanded the indications for M-TEER in patients with DMR. The safety and efficacy of iterated versions of the MitraClip device were demonstrated in the EXPAND and EXPAND G4 studies in a broader spectrum of degenerative anatomies in an all-comers patient population from routine clinical practice.[2-4] Both EXPANDed studies enrolled 2,205 subjects across 91 centers in the United States, Europe, Canada, Israel, Saudi Arabia, and Japan from 2018 to 2022 of whom 846 patients were treated for echocardiographic core laboratory-rated DMR. The first EXPAND study analyzed the third-generation MitraClip system and MR in degenerative anatomies, which were reduced to grade ≤1+ in 79% at 1-year follow-up (93.8% MR grade ≤2+).[2] The fourth-generation MitraClip system was assessed in the second EXPAND G4 study, and therein, MR reduction was further improved to grade ≤1+ in 89% of patients with DMR at 1 year (97.7% MR grade ≤2+).[3] Equal results between the MitraClip and the PASCAL system (Edward Lifesciences) were demonstrated in a randomized trial for M-TEER in DMR.[5,6] The postmarket MiCLASP study analyzed outcomes of the PASCAL system and reported a 1-year reduction of MR to grade ≤1+ in 82% of patients undergoing M-TEER for DMR along with high survival and freedom from heart failure hospitalization (HFH), reductions in symptoms, and improvements in functional capacity and quality of life.[7] Thus, results in patients with DMR undergoing M-TEER in clinical practice are generally excellent. However, further insights into the results of postmarket registries and the anatomies treated therein are required to promote the expansion of indications and to understand potential limits of M-TEER.

From the surgical experience, mitral valve repair of the anterior leaflet is known to be more complex compared with isolated posterior mitral leaflet disease. Historically, surgical mitral valve repair achieved inferior outcomes in patients with anterior leaflet disease.[8,9] However, advances in technology and experience of mitral valve surgery improved results. Presently, surgical outcomes of anterior and bileaflet repair are comparable with those of posterior leaflet repair, while anterior repair is still technically more challenging, leading to longer bypass and cross-clamp times and higher incidences of recurrent MR.[10,11] In contrast, the relevance of disease location in patients with DMR undergoing M-TEER is unknown.

In this issue of *JACC: Cardiovascular Interventions*, Kar et al[12] analyzed the impact of anterior, posterior, and bileaflet disease on outcomes following M-TEER in patients with DMR, on the basis of data from the

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EXPANDed studies. The investigators demonstrate that M-TEER of DMR improves outcomes, regardless of the affected leaflet(s). This subanalysis of the EXPANDed studies included only patients with prolapse or flail and echocardiographic core laboratory-assessed disease location. Patients were categorized according to the location of prolapse or flail as follows: anterior only (prolapse or flail at A1, A2, and/or A3), posterior only (prolapse or flail at P1, P2, and/or P3), or bileaflet disease (prolapse or flail at any combination of A1, A2, and A3 and P1, P2, and P3). Among 556 core laboratory-assessed patients, prolapse or flail was located at the anterior, posterior, or both leaflets in 19%, 70%, and 11% of cases, respectively.

The mean patient age ranged from 79 to 81 years and Society of Thoracic Surgeons repair score from 4.8% to 5.3% among the groups. Patients in the anterior leaflet group were sicker compared with the posterior and bileaflet groups, having larger left ventricular volumes and higher event rates of HFH (anterior 46% vs posterior 32% and bileaflet 32%; $P < 0.05$) before M-TEER. Mean left ventricular ejection fraction varied slightly among groups (anterior 60%, posterior 62%, and bileaflet 57%; $P < 0.01$). Notably, 29% of patients (159 of 553) had complex anatomies. Reasons for anatomical complexity included primary jets outside the A2-P2 segment, severely degenerated leaflets, wide flail gaps and widths, bileaflet disease, and calcified landing zones. The investigators report comparably low device (42-46 min) and procedural (82-84 min) times for M-TEER among groups. A mean of 1.4 to 1.5 MitraClips were used, and the MitraClip XTW was the most frequently applied device in all groups. Acute procedural success, defined as achievement of residual MR grade $\leq 2+$ at the time of discharge, was high and without statistically significant differences among groups (92%-98%). Major adverse event rates at 30 days, defined as death, myocardial infarction, stroke, mitral valve replacement, single-leaflet device attachment, and device embolization, were low across all groups (anterior 3.8%, posterior 4.4%, and bileaflet 6.6%; $P = 0.65$). Specifically, the rate of single-leaflet device attachment was 1.6% across groups. Through 1 year, all groups showed strong reductions in MR severity from baseline. MR was reduced to $\leq 1+$ in 93%, 82%, and 97% of subjects with primarily anterior, posterior, and bileaflet pathologies, respectively ($P = 0.15$). Furthermore, patients in all 3 groups experienced substantial improvements in quality of life from baseline to 1-year follow-up. Remarkably, the median Kansas City Cardiomyopathy Questionnaire score improvement was >15 points in all 3 groups and thus can be considered as a large change in quality of life.[13] Finally, rates of all-cause mortality and HFH at 1 year were similar among groups (composite of all-cause mortality and HFH: anterior 23%, posterior 14.8%, and bileaflet 15.9%; $P = 0.15$).

Strengths of the study are the large number of patients analyzed from an all-comers scenario as well as the echocardiography core laboratory analysis of baseline mitral valve anatomy and MR extent. Limitations of the study are the limited follow-up duration of 1 year after M-TEER and the limited echocardiographic follow-up rate of 55%. Likewise, potential result bias could be caused by the use of different devices. In the bileaflet group, 100% of patients were treated with the advanced fourth-generation MitraClip system. In the posterior and anterior groups, the fourth-generation device was used in 69% and 71% of cases, respectively, while the other patients were treated with the third-generation MitraClip System. Although the EXPANDed studies included all-comers populations, patients with challenging pathologies and estimation of suboptimal technical results might be excluded from the registries on the basis of the discretion of the interventionalists. Notably, a significant cleft was present in only 1 patient (<0.2%), small valve areas with the risk for generating mitral valve stenosis after M-TEER were present in only 2 patients (<0.4%), and significant calcifications in the clip landing zone were identified in only 12 patients (2.1%). Myxoid leaflet degeneration with multisegmented large prolapses, known as Barlow's disease, was not described. Thus, anatomically highly challenging cases seemed to be excluded from this registry. In this regard, the investigators do not present a detailed outcome analysis after stratification by individual criteria for anatomical complexity or after stratification by prolapse or flail location in a central vs commissural position. Furthermore, the results may not apply to DMR beyond prolapse or flail. Considering the elderly patient cohort with an increased rate of HFH prior to M-TEER and advanced surgical risk, the outcomes of this study cannot be compared with those of surgical registries with younger and overall healthier patients.

In summary, the study adds another important piece to the puzzle to further elucidate the importance and clinical relevance of M-TEER in DMR. Design improvements of the latest M-TEER generations, increased operator experience and improved imaging technology along with the availability of different clip widths and lengths set the stage for an individualized treatment of yet more complex pathologies. The study of Kar et al[12] represents the current clinical practice of M-TEER with the use of new-generation MitraClip devices in a modern and experienced era of

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transcatheter therapy. The results demonstrate that transcatheter repair is equally feasible among patients with anterior or posterior leaflet prolapse or flail. Technical difficulties in the repair of anterior leaflet disease as known from the surgical world are not observed with M-TEER. However, more studies in patients with extreme pathologies are required to further push the boundaries of M-TEER and to understand potential limits of the therapy. Furthermore, results from the ongoing randomized trials (REPAIR MR and PRIMARY) with comparison between modern transcatheter and surgical repair and long-term follow-up are required to demonstrate the relevance of M-TEER in younger, low-risk patients.

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**KEY WORDS** anatomic complexity, mitral regurgitation, M-TEER, transcatheter therapy

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