

## STATE-OF-THE-ART REVIEW

# Durability of Mitral Valve Transcatheter Edge-to-Edge Repair

## An Expert Overview



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### ABSTRACT

**BACKGROUND** Mitral regurgitation (MR) is a globally endemic heart disease burden with significant morbidity and mortality. Mitral transcatheter edge-to-edge repair (M-TEER) has emerged as a minimally invasive treatment with established safety and intermediate-term efficacy.

**OBJECTIVES** The aim of this study was to determine M-TEER durability and the incidence, risk factors, and treatment strategies of M-TEER failure.

**METHODS** A comprehensive literature review was performed, identifying 457 records, from which 33 full-text papers were included. Definitions of MR recurrence, reintervention, and M-TEER durability and failure were provided. On the basis of these definitions, weighted means with 95% CIs were calculated for the rates of MR recurrence, reintervention, and their composite for both the overall population and the primary and secondary MR subgroups.

**RESULTS** The pooled weighted means of MR recurrence and reintervention ranged between 5% and 10% in the first months after the index procedure, remained relatively stable for the first 3 years, and increased at 5 years to 17% and 9%, respectively. MR recurrence and reintervention weighted means were numerically higher in primary than secondary MR, and 41% of primary MR patients experienced MR recurrence or reintervention at 5 years. Redo transcatheter edge-to-edge repair for M-TEER failure seemed safer than surgery but was associated with 1-year MR recurrence rates between 20% and 40%. Mitral valve replacement was the most common surgical technique for M-TEER failure.

**CONCLUSIONS** The incidence of M-TEER failure after a successful index procedure increases after 3 years and is more pronounced with primary than secondary MR. More systematic, longer term follow-up data after M-TEER are required to better define M-TEER durability. (JACC Cardiovasc Interv. 2026;19:1057-1070) © 2026 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY license (<http://creativecommons.org/licenses/by/4.0/>).

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The author attests they are in compliance with human studies committees and animal welfare regulations of the author's institution and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the [Author Center](#).

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## ABBREVIATIONS AND ACRONYMS

**APS** = acute procedural success

**HFREF** = heart failure with reduced ejection fraction

**LLI** = loss of leaflet insertion

**LV** = left ventricle/ventricular

**MAC** = mitral annular calcification

**MR** = mitral regurgitation

**M-TEER** = mitral transcatheter edge-to-edge repair

**RCT** = randomized controlled trial

**SLDA** = single-leaflet device attachment

**M**itral regurgitation (MR) is the second most frequent valvular heart disease in the Western world, with approximately 10% of individuals  $\geq 75$  years of age having clinically relevant MR.<sup>1,2</sup> If left untreated, MR will lead to adverse cardiac remodeling with left ventricular (LV) dilatation, impaired LV function, pulmonary hypertension, tricuspid regurgitation, and progressive right ventricular failure, which coincide with poor functional status and increased mortality.<sup>3</sup> Mitral transcatheter edge-to-edge repair (M-TEER) is a catheter-based technique to repair primary or secondary MR through mitral leaflet approximation.<sup>4-6</sup> To date, more than 200,000 patients have been

treated with M-TEER worldwide.<sup>7,8</sup> A wealth of data have established the procedural safety and short- to intermediate-term efficacy of M-TEER, but there remains a knowledge gap regarding its durability. Hence, we performed a comprehensive literature review on M-TEER durability and covered the incidence rates, risk factors, and treatment strategies of M-TEER failure.

## METHODS

This narrative review followed the Scale for the Assessment of Narrative Review Articles guidelines.<sup>9</sup> A comprehensive search of electronic databases, including PubMed, Web of Science, Excerpta Medica, and Google Scholar, was conducted to identify relevant studies published from January 1, 2003, until May 15, 2025. We also investigated studies listed as references in the selected papers. Randomized controlled trials (RCTs) and observational studies with at least 1-year follow-up were considered. Accordingly, 457 records were identified, of which 33 full-text papers were retained, as displayed in **Figure 1**. The following search terms or phrases were used: “mitral valve regurgitation,” “mitral transcatheter edge-to-edge repair,” “m-TEER,” “MitraClip device,” “PASCAL device,” “durability,” “durability of m-TEER,” “durability of mitral transcatheter edge-to-edge repair,” “m-TEER long-term results,” “mitral transcatheter edge-to-edge repair long-term results,” “m-TEER long-term outcomes,” “mitral transcatheter edge-to-edge repair long-term outcomes,” and “mitral regurgitation recurrence after mitral transcatheter edge-to-edge repair.” Moreover, papers on risk factors for M-TEER failure and on the types of reintervention were analyzed.

## HIGHLIGHTS

- M-TEER durability up to 5 years remains understudied.
- M-TEER failure increases after 3 years and more so in primary than secondary MR.
- MR recurrence rates are relatively high after redo M-TEER.
- Prospective studies with more systematic and longer-term follow-up are needed.

Institutional Review Board approval and patient consent were not required, as all data were previously published and publicly available.

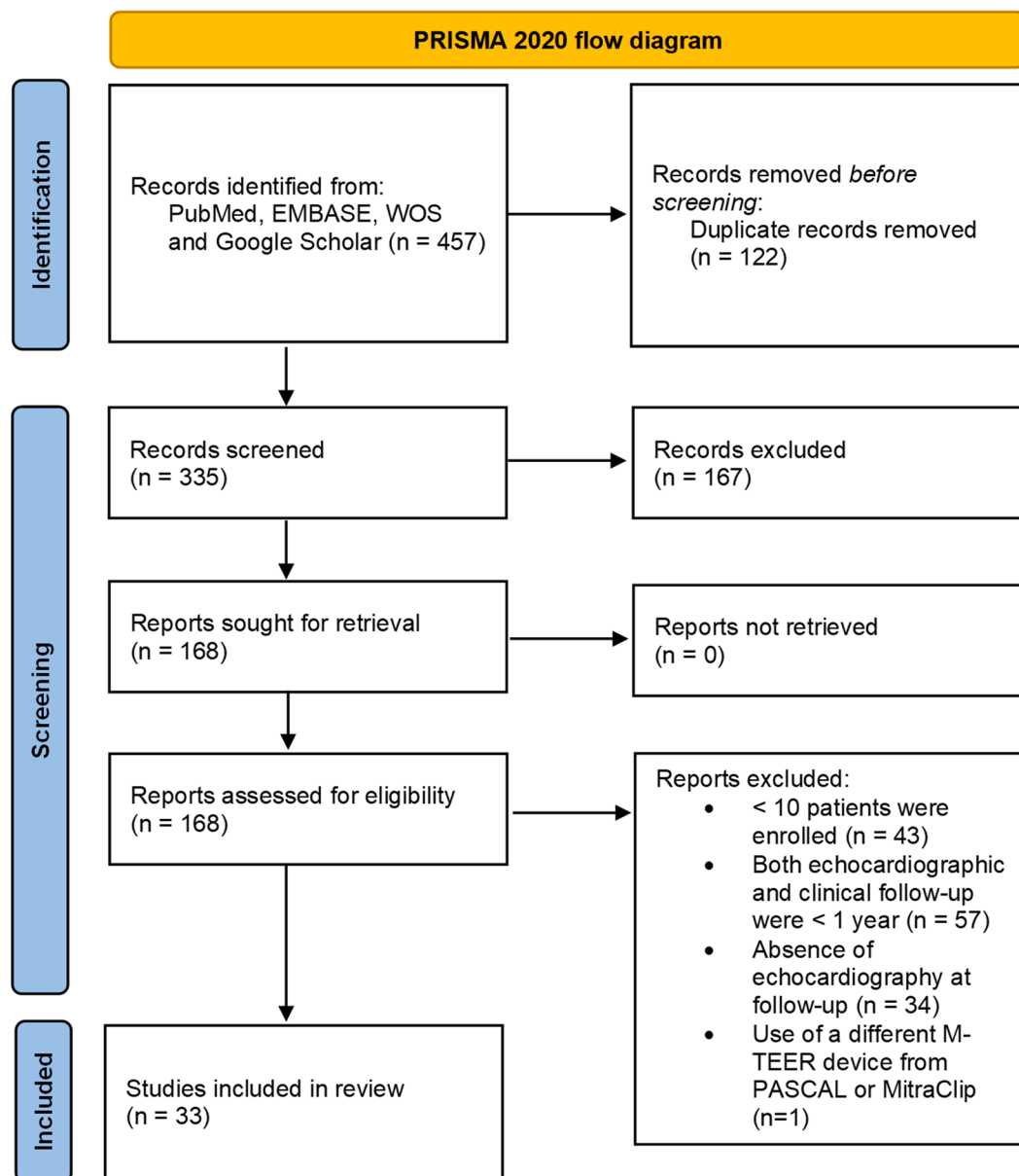
**DEFINITIONS.** The Mitral Valve Academic Research Consortium defined structural and functional device failure. Structural failure refers to a device malfunction. It includes device fracture, migration or embolization, single-leaflet device attachment (SLDA) and loss of leaflet insertion (LLI) that can be due to leaflet tear or perforation or prolapse. Functional failure is characterized by moderate-to-severe or greater MR in the presence of a device that performs as intended.<sup>10</sup>

We considered M-TEER durability as the long-term integrity of the repair with a sustained reduction in MR. Durability represents the long-term freedom from MR recurrence and reintervention. M-TEER failure was the composite of MR recurrence and repeat intervention, with MR recurrence defined as an increase in MR of at least 1 grade in comparison with the residual MR at the end of the index procedure and to at least moderate-to-severe ( $\geq 3+$ ).<sup>11,12</sup> To determine MR recurrence, we accounted for acute procedural success (APS).<sup>10</sup> MR recurrence rates were extracted as reported in the original studies. If not explicitly stated, these rates were calculated as 1 minus the proportion of patients with MR  $\leq 2+$  at follow-up. Redo M-TEER and surgical mitral valve repair or replacement were used to calculate the reintervention rates.

We determined the main mechanism of MR recurrence and repeat intervention (ie, structural or functional) from studies on reintervention after M-TEER failure.

**STATISTICAL ANALYSIS.** For each time point during follow-up (time points ranging from 1 to 5 years and depending on availability and reporting within individual studies), weighted means with 95% CIs were

**FIGURE 1** Flowchart of the Study Selection Process



Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram. M-TEER = mitral transcatheter edge-to-edge repair; WOS = Web of Science.

calculated for the rates of MR recurrence, reintervention, and their composite using the inverse variance weighting method for both the overall population and the primary and secondary MR subgroups. The extracted proportions were first transformed using the Freeman-Tukey double arcsine method because of some relatively low numbers.<sup>13</sup> Subsequently, inverse variance weighted fixed and

random effects analyses were performed, and according to heterogeneity ( $I^2$ ) between studies, 1 of these 2 models was preferred over the other (the DerSimonian-Laird random-effects approach was used when  $I^2$  was  $>25\%$ ).<sup>14</sup> Then the resulting proportions were transformed back. [Supplemental Tables 1 to 3](#) report the heterogeneity of variance components of the weighted means for the overall

population and the etiology subgroups, respectively. Moreover, to avoid excessive heterogeneity, the annual weighted means for primary and secondary MR were calculated only using the studies that reported both etiologies. Weighted means with 95% CIs are presented graphically with plots, where the dimension of the circle is proportional to the weight (inverse of the pooled variance). Statistical analyses were performed using R version 4.5.0 (R Foundation for Statistical Computing).

## RESULTS

**M-TEER DURABILITY UP TO 1 YEAR.** Twenty-two studies reported MR recurrence and/or reintervention rates at 1-year follow-up (Table 1, Figures 2A and 2B).<sup>11,12,15-35</sup>

In the ACCESS-EU (ACCESS-Europe: A Two-Phase Observational Study of the MitraClip System in Europe) study, a prospective, multicenter real-world registry enrolling 567 high-risk patients who underwent M-TEER with the early-generation MitraClip device (Abbott Cardiovascular) for predominantly secondary MR, MR recurrence was reported in 20% at 1 year. Structural failure, namely, SLDA, was described in 27 patients (4.8%), of whom 16 (4.1%) needed reintervention (10 repeat M-TEER and 6 surgery).<sup>17</sup> The EXPAND (A Contemporary, Prospective Study Evaluating Real-world Experience of Performance and Safety for the Next Generation of MitraClip® Devices) and EXPAND G4 (A Post-Market Study Assessment of the Safety and Performance of the MitraClip G4 System) studies enrolled 1,041 and 1,164 patients with at least moderate-to-severe ( $\geq 3+$ ) MR, irrespective of etiology, who underwent M-TEER with third- and fourth-generation MitraClip devices, respectively. APS was 95.9% in EXPAND and 97.8% in EXPAND G4, and MR recurrence and repeat intervention at 12 months were 2.5% and 1.7% and 1.9% and 4.2%, respectively, with no differences in event rates between primary and secondary MR.<sup>30,31</sup>

In the COAPT (Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients With Functional Mitral Regurgitation) trial, 302 patients with heart failure with reduced ejection fraction (HFrEF) underwent MitraClip M-TEER for secondary MR, achieving an APS of 95%. One-year MR recurrence and reintervention were 5.2% and 2.9%, respectively.<sup>21</sup> The MITRA-FR (Multicentre Study of Percutaneous Mitral Valve Repair MitraClip Device in Patients With Severe Secondary Mitral Regurgitation) RCT included 152 HFrEF patients who underwent M-TEER with the MitraClip for at least moderate-to-severe secondary

MR. Echocardiographic data are available up to 1 year, with MR recurrence of 17.5%, while repeat intervention rates were not reported.<sup>22</sup>

In the randomized MATTERHORN (A Multicenter, Randomized, Controlled Study to Assess Mitral Valve Reconstruction for Advanced Insufficiency of Functional or Ischemic Origin) trial, 104 patients with moderate-to-severe secondary MR and HFrEF underwent M-TEER. At 1 year, MR recurrence was 8.9% and reintervention 5%.<sup>33</sup> In RESHAPE-HF2 (Randomised Investigation of the MitraClip Device in Heart Failure: 2nd Trial in Patients With Clinically Significant Functional Mitral Regurgitation), which included 250 patients with HFrEF and secondary MR, MR recurrence after M-TEER occurred in 9.6% at 1 year and reintervention in 2% at 2 years.<sup>34</sup>

In the EVEREST II (Endovascular Valve Edge-to-Edge Repair Study) RCT of 178 M-TEER-treated patients (75% with primary MR and 25% with secondary MR), MR recurrence was 21% and reintervention was 23.2% at 1 year.<sup>15</sup>

In the multicenter EuroSMR (European Registry of Transcatheter Repair for Secondary Mitral Regurgitation) registry, which included 1,628 patients with 3+/4+ secondary MR, MR recurrence at 1 year was 3.9%. Repeat intervention rates were not reported.<sup>25</sup>

In the randomized CLASP IID (Edwards PASCAL Transcatheter Valve Repair System Pivotal Clinical Trial) trial (300 patients with primary MR randomized 2:1 to PASCAL [Edwards Lifesciences] and MitraClip), device success (98.5% vs 98.9%;  $P = 1.000$ ) was similar for PASCAL and MitraClip M-TEER. MR recurrence was 4.2% for PASCAL and 6.2% for MitraClip, and reintervention was 2.1% for both devices.<sup>32</sup>

The weighted means of 1-year MR recurrence (13.4% vs 3.4%, respectively) and reintervention (4.5% vs 3.2%, respectively) between older and newer devices are presented in Figure 2C. Newer devices are characterized by the independent grasping feature.<sup>12,15-24,26-28,30-33,35</sup>

**M-TEER DURABILITY BEYOND 1-YEAR FOLLOW-UP.** Data on MR recurrence and/or repeat intervention beyond the first year are available for 15 studies, as summarized in Table 2 and Figures 2D to 2F.<sup>11,20,26,34-47</sup>

The CLASP (Edwards PASCAL Transcatheter Valve Repair System) study included 124 patients (69% with secondary MR and 31% with primary MR) and reported MR recurrence at 3 years after M-TEER with PASCAL in 7% and reintervention in 4%. However, MR recurrence values should be interpreted with caution because echocardiographic follow-up at

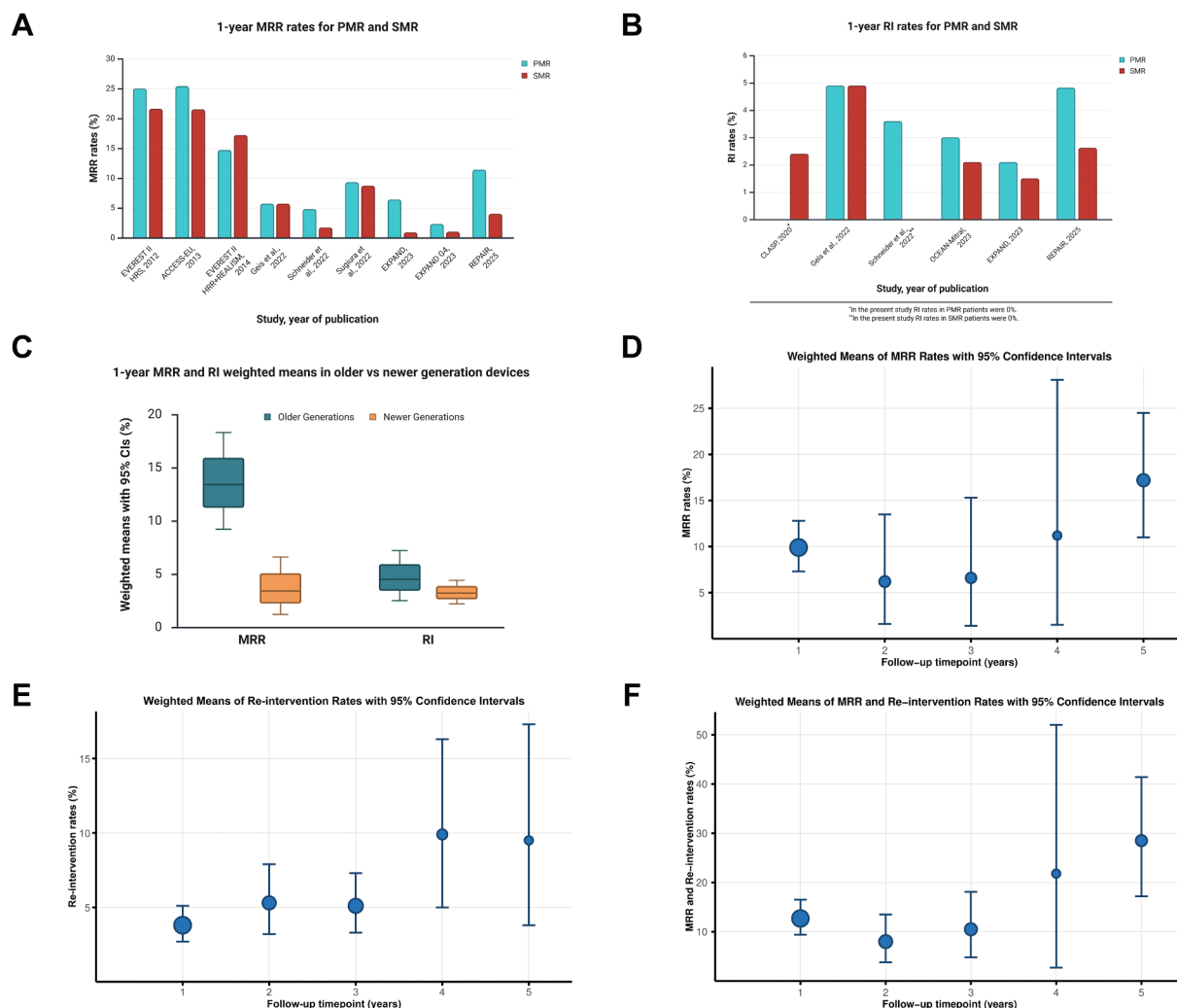
**TABLE 1 M-TEER Durability up to 1-Year Follow-Up**

| Study<br>First Author (Year)                              | Prospective<br>Study | N*                                       | Device                                                                              | MR Etiology                              | MRR                                | RI                                 |
|-----------------------------------------------------------|----------------------|------------------------------------------|-------------------------------------------------------------------------------------|------------------------------------------|------------------------------------|------------------------------------|
| EVEREST II<br>Feldman et al (2011) <sup>15</sup>          | Yes                  | 258<br>(178 MitraClip vs 80<br>MVS)      | MitraClip first generation                                                          | 75% PMR, 25%<br>SMR                      | 21%                                | 23.2%                              |
| EVEREST II HRS<br>Whitlow et al (2012) <sup>16</sup>      | Yes                  | 78                                       | MitraClip first generation                                                          | 41% PMR, 59%<br>SMR                      | 22.2%                              | 1.3%                               |
| ACCESS-EU<br>Maisano et al (2013) <sup>17</sup>           | Yes                  | 567                                      | MitraClip first generation                                                          | 31% PMR, 69%<br>SMR                      | 20%                                | 4.1%                               |
| EVEREST II REALISM<br>Glower et al (2014) <sup>18</sup>   | Yes                  | 351                                      | MitraClip first generation                                                          | 30% PMR, 70%<br>SMR                      | 16.4%                              | 2.1%                               |
| GRASP<br>Scandura et al (2016) <sup>19</sup>              | Yes                  | 180                                      | MitraClip first generation                                                          | 18.3% PMR, 81.7%<br>SMR                  | 14.1%                              | 0%                                 |
| COAPT<br>Stone et al (2018) <sup>21</sup>                 | Yes                  | 614<br>(302 MitraClip vs<br>312 GDMT)    | MitraClip first generation                                                          | 0% PMR, 100%<br>SMR                      | 5.2%                               | 2.9%                               |
| MITRA-FR<br>Obadia et al (2018) <sup>22</sup>             | Yes                  | 304<br>(152 MitraClip vs<br>152 GDMT)    | MitraClip first generation                                                          | 0% PMR, 100%<br>SMR                      | 17.5%                              | NA                                 |
| EVEREST II IDE<br>Ailawadi et al (2019) <sup>23</sup>     | Yes                  | 616                                      | MitraClip first generation                                                          | 0% PMR, 100%<br>SMR                      | 15.5%                              | 7.1%                               |
| CLASP<br>Webb et al (2020) <sup>24</sup>                  | Yes                  | 124                                      | PASCAL first and second<br>generations                                              | 31% PMR, 69%<br>SMR                      | 0%                                 | 1.6%                               |
| EuroSMR<br>Koell et al (2021) <sup>25</sup>               | No                   | 1,676                                    | MitraClip first to fourth<br>generations                                            | 0% PMR, 100%<br>SMR                      | 3.9%                               | NA                                 |
| Schneider et al (2022) <sup>27</sup>                      | No                   | 412<br>(216 MitraClip and<br>196 PASCAL) | MitraClip third and fourth<br>generations<br>PASCAL first and second<br>generations | 51% PMR, 49%<br>SMR                      | 3.4% (MitraClip), 4.8%<br>(PASCAL) | 1% (MitraClip),<br>2.1% (PASCAL)   |
| Geis et al (2022) <sup>28</sup>                           | No                   | 123<br>(82 MitraClip and<br>41 PASCAL)   | MitraClip third generation<br>PASCAL first and second<br>generations                | 37.4% PMR, 62.6%<br>SMR                  | 6.1% (MitraClip), 4.8%<br>(PASCAL) | 6.1% (MitraClip), 2.4%<br>(PASCAL) |
| Sugiura et al (2022) <sup>12</sup>                        | No                   | 685                                      | MitraClip first to third<br>generations                                             | 37.6% PMR, 62.4%<br>SMR                  | 9.8%                               | 6%                                 |
| OCEAN-Mitral<br>Kubo et al (2023) <sup>29</sup>           | No                   | 2,150                                    | MitraClip second and fourth<br>generation                                           | 34.6% PMR,<br>65.4% SMR                  | 5.9%                               | 2.4%                               |
| EXPAND<br>Kar et al (2023) <sup>30</sup>                  | Yes                  | 1,041                                    | MitraClip third generation                                                          | 50.5% PMR,<br>49.5% SMR                  | 2.5%                               | 1.9%                               |
| EXPAND G4<br>von Bardeleben et al<br>(2023) <sup>31</sup> | Yes                  | 1,164                                    | MitraClip fourth generation                                                         | 43% PMR, 57%<br>SMR                      | 1.7%                               | 4.2%                               |
| CLASP IID<br>Zahr et al (2023) <sup>32</sup>              | Yes                  | 300<br>(96 MitraClip vs<br>204 PASCAL)   | MitraClip third and fourth<br>generations<br>PASCAL first to third<br>generations   | 100% PMR, 0%<br>SMR                      | 6.2% (MitraClip), 4.2%<br>(PASCAL) | 2.1% (MitraClip),<br>2.1% (PASCAL) |
| MATTERHORN<br>Baldus et al (2024) <sup>33</sup>           | Yes                  | 208<br>(104 MitraClip vs<br>104 MVS)     | MitraClip first and second<br>generations                                           | 0% PMR, 100%<br>SMR                      | 8.9%                               | 5%                                 |
| REPAIR<br>von Stein et al (2025) <sup>35</sup>            | No                   | 2,165                                    | PASCAL first to third<br>generations                                                | 47% PMR, 52%<br>SMR,<br>1% indeterminate | 7.7%                               | 4.5%                               |

Studies that evaluated 1-year M-TEER durability are listed, ordered by year of publication. \*The total number of patients included in the study is reported. When two subgroups are reported, the use of "vs" (rather than "and") indicates that the study was a randomized controlled trial.

ACCESS-EU = ACCESS-Europe: A Two-Phase Observational Study of the MitraClip System in Europe; CLASP = Edwards PASCAL Transcatheter Valve Repair System; CLASP IID = Edwards PASCAL Transcatheter Valve Repair System Pivotal Clinical Trial; COAPT = Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients With Functional Mitral Regurgitation; EuroSMR = European Registry of Transcatheter Repair for Secondary Mitral Regurgitation; EVEREST II = Endovascular Valve Edge-to-Edge Repair Study; EVEREST II HRS = EVEREST II High Risk Study; EVEREST II REALISM = EVEREST II Real World Expanded Multicenter Study; EXPAND = A Contemporary, Prospective Study Evaluating Real-world Experience of Performance and Safety for the Next Generation of MitraClip® Devices; EXPAND G4 = A Post-Market Study Assessment of the Safety and Performance of the MitraClip G4 System; GDMT = guideline-directed management and therapy; GRASP = Getting Reduction of Mitral Insufficiency by Percutaneous Clip Implantation; IDE = Investigational Device Exemption; MATTERHORN = A Multicenter, Randomized, Controlled Study to Assess Mitral Valve Reconstruction for Advanced Insufficiency of Functional or Ischemic Origin; MITRA-FR = Multicentre Study of Percutaneous Mitral Valve Repair MitraClip Device in Patients With Severe Secondary Mitral Regurgitation; MR = mitral regurgitation; MRR = mitral regurgitation recurrence; M-TEER = mitral transcatheter edge-to-edge repair; MVS = mitral valve surgery; NA = not available; OCEAN-Mitral = Optimized Catheter Valvular Intervention; PMR = primary mitral regurgitation; REPAIR = Registry of PASCAL for Mitral Regurgitation; RI = repeat intervention; SMR = secondary mitral regurgitation.

**FIGURE 2 1-Year MRR and Reintervention Rates From Single Studies by Etiology and Weighted Means Analyses by Device Generation and Follow-Up Duration**



(A) One-year mitral regurgitation recurrence (MRR) rates for primary mitral regurgitation (PMR) and secondary mitral regurgitation (SMR) patients. Only studies with 1-year MRR rates for both PMR and SMR were selected.<sup>12,16-18,21,26-28,30,31,33,35,36,44,45,47</sup> (B) One-year repeat intervention (RI) rates for PMR and SMR patients. Only studies with 1-year RI rates for both PMR and SMR were selected.<sup>24,27-30,35</sup> (C) One-year MRR and RI weighted means with 95% CIs in older vs newer generation devices. Studies that allowed differentiation of durability outcomes between older and newer devices or that used only 1 type of iteration (older or newer) were included.<sup>12,15-24,26-28,30-33,35</sup> (D) Weighted means with 95% CIs of MRR rates at different time points for the total patient population (the DerSimonian-Laird random-effects approach was used for all the estimates). (E) Weighted means with 95% CIs of RI rates at different time points for the total patient population (the DerSimonian-Laird random-effects approach was used for all the estimates). (F) Weighted means with 95% CIs of MRR and RI rates (mitral transcatheter edge-to-edge repair failure) at different time points for the total patient population (the DerSimonian-Laird random-effects approach was used for all the estimates). ACCESS-EU = ACCESS-Europe: A Two-Phase Observational Study of the MitraClip System in Europe; CLASP = Edwards PASCAL Transcatheter Valve Repair System; EVEREST II HRS = Endovascular Valve Edge-to-Edge Repair Study High Risk Study; EXPAND = A Contemporary, Prospective Study Evaluating Real-world Experience of Performance and Safety for the Next Generation of MitraClip® Devices; EXPAND G4 = A Post-Market Study Assessment of the Safety and Performance of the MitraClip G4 System; OCEAN-Mitral = Optimized Catheter Valvular Intervention; REPAIR = Registry of PASCAL for Mitral Regurgitation.

3 years was missing in approximately one-half of the study population.<sup>39</sup> In a mixed cohort from the EVEREST I and II trials (79% with primary MR and 21% with secondary MR), MR recurrence and

reintervention rates after MitraClip M-TEER were 21% and 21.9% at 3 years.<sup>36</sup> In the EVEREST II High Risk Study, in which 78 patients with 3+/4+ MR at extreme or prohibitive

**TABLE 2 M-TEER Durability Beyond 1-Year Follow-Up**

| Study<br>First Author (Year)                       | Prospective<br>Study | N <sup>a</sup>                        | Device                                                                       | MR Etiology                           | Follow-Up<br>Length | MRR                | RI                |
|----------------------------------------------------|----------------------|---------------------------------------|------------------------------------------------------------------------------|---------------------------------------|---------------------|--------------------|-------------------|
| Lesevic et al (2017) <sup>20</sup>                 | No                   | 144                                   | MitraClip first generation                                                   | 55% PMR, 45% SMR                      | 2 y                 | 19.5% <sup>b</sup> | 16%               |
| Ooms et al (2022) <sup>26</sup>                    | No                   | 241                                   | MitraClip first to third generations                                         | 0% PMR, 100% SMR                      | 2 y                 | 21% <sup>b</sup>   | 8.2%              |
| RESHAPE-HF2<br>Anker et al (2024) <sup>34</sup>    | Yes                  | 505<br>(250 MitraClip vs<br>255 GDMT) | MitraClip first to fourth generations                                        | 0% PMR, 100% SMR                      | 2 y                 | 9.6% <sup>b</sup>  | 2%                |
| REPAIR<br>von Stein et al (2025) <sup>35</sup>     | No                   | 2,165                                 | PASCAL first to third generations                                            | 47% PMR, 52% SMR,<br>1% indeterminate | 2 y                 | 5.9%               | 5.3%              |
| EVEREST I+II<br>Feldman et al (2009) <sup>36</sup> | Yes                  | 107                                   | MitraClip first generation                                                   | 79% PMR, 21% SMR                      | 3 y                 | 21%                | 21.9%             |
| Freixa et al (2022) <sup>37</sup>                  | No                   | 1,028                                 | MitraClip first to third generations                                         | NA                                    | 3 y                 | 17.9% <sup>c</sup> | 4%                |
| CLASP<br>Spargias et al (2023) <sup>39</sup>       | Yes                  | 124                                   | PASCAL first and second generations                                          | 31% PMR, 69% SMR                      | 3 y                 | 7%                 | 4%                |
| TRAMI<br>Kalbacher et al (2018) <sup>40</sup>      | Yes                  | 799                                   | MitraClip first generation                                                   | 30.7% PMR, 69.3% SMR                  | 4 y                 | NA                 | 11.7%             |
| McKellar et al (2023) <sup>11</sup>                | No                   | 660<br>(267 M-TEER<br>and 393 MVS)    | MitraClip first to fourth generations<br>PASCAL first and second generations | NA                                    | 4 y                 | 25.5% <sup>b</sup> | 7.5%              |
| EVEREST II<br>Feldman et al (2015) <sup>42</sup>   | Yes                  | 258<br>(178 MitraClip vs<br>80 MVS)   | MitraClip first generation                                                   | 75% PMR, 25% SMR                      | 5 y                 | 11.5% <sup>d</sup> | 5.7% <sup>d</sup> |
| EVEREST II HRS<br>Kar et al (2019) <sup>43</sup>   | Yes                  | 78                                    | MitraClip first generation                                                   | 41% PMR, 59% SMR                      | 5 y                 | 10.7%              | 7.14%             |
| Buzzatti et al (2019) <sup>44</sup>                | No                   | 353                                   | MitraClip first and second generations                                       | 27.5% PMR, 68.6% SMR                  | 5 y                 | 25.8%              | 5%                |
| Öztürk et al (2021) <sup>45</sup>                  | No                   | 265                                   | MitraClip first generation                                                   | 40% PMR, 60% SMR                      | 5 y                 | 26%                | 9.5%              |
| COAPT<br>Stone et al (2023) <sup>46</sup>          | Yes                  | 614<br>(302 MitraClip vs<br>312 GDMT) | MitraClip first generation                                                   | 0% PMR, 100% SMR                      | 5 y                 | 5.3%               | 4.5%              |
| EuroSMR<br>Stocker et al (2024) <sup>47</sup>      | No                   | 1,628                                 | MitraClip first to fourth generations                                        | 0% PMR, 100% SMR                      | 5.4 y               | 14.5%              | NA                |

Studies that evaluated M-TEER durability beyond the first year of follow-up are listed. Longest data available are reported, and studies are ordered by follow-up length; among the same follow-up length, studies are ordered by year of publication. <sup>a</sup>The total number of patients included in the study is reported. When two subgroups are reported, the use of "vs" (rather than "and") indicates that the study was a randomized controlled trial. <sup>b</sup>Rates recorded at 1-year follow-up. <sup>c</sup>Rates recorded at 2-year follow-up. <sup>d</sup>Rates are considered between 6 months and 5 years from the procedure.

RESHAPE-HF2 = Randomised Investigation of the MitraClip Device in Heart Failure: 2nd Trial in Patients With Clinically Significant Functional Mitral Regurgitation; TRAMI = Transcatheter Mitral Valve Interventions; other abbreviations as in [Table 1](#).

surgical risk (Society of Thoracic Surgeons score  $\geq 12\%$ ) underwent MitraClip implantation with APS of 71.8%, MR recurrence was 10.7% and repeat intervention was 7.14% after 5 years of follow-up.<sup>43</sup>

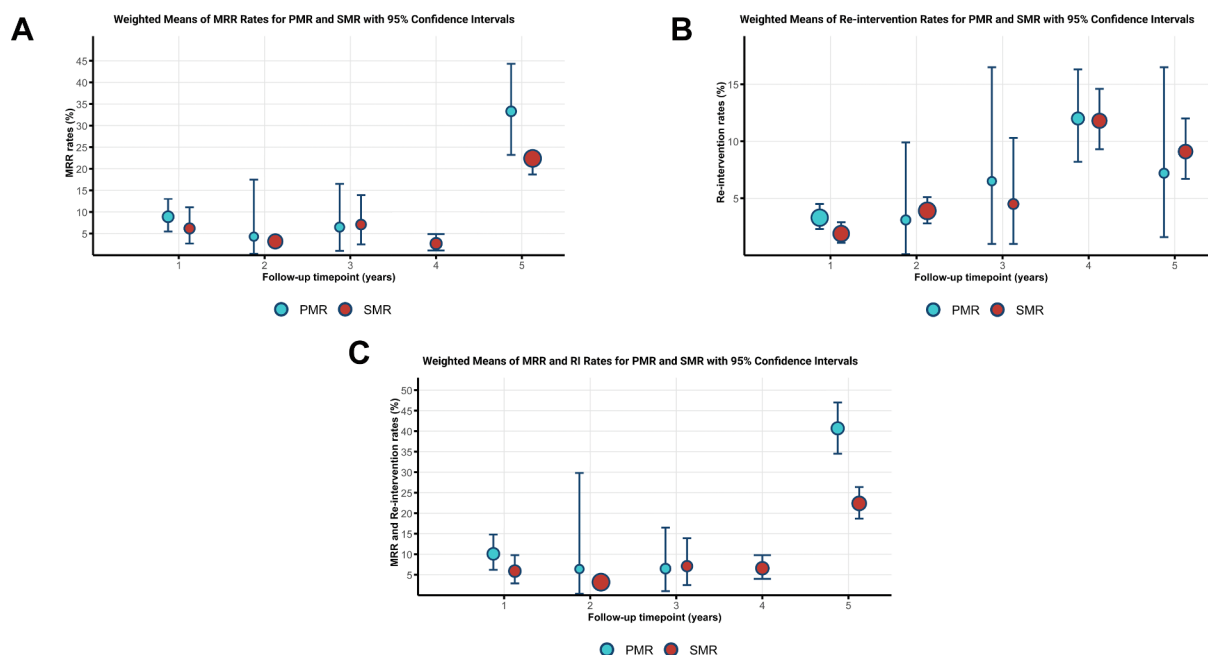
In the EVEREST II RCT, MR recurrence was 12.3% and reintervention was 27.9% at 5 years. A 6-month landmark analysis revealed that most repeat interventions had occurred within 6-month follow-up for inadequate MR reduction during the index procedure (residual MR and no APS) or early SLDA. Between 6 months and 5 years, MR recurrence was 11.5% and reintervention was 5.7%.<sup>42</sup> In the COAPT trial, MR recurrence was 5.3% and reintervention was 4.5% at 5 years.<sup>46</sup>

Single-center registries from Italy (n = 353) and Germany (n = 265) that included patients with

primary and secondary MR reported 5-year MR recurrence in 26% in both studies and reintervention in 5% and 9.6%, respectively.<sup>44,45</sup>

In the multicenter EuroSMR registry, at a median follow-up of 5.4 years (Q1-Q3: 4.6-6.6 years), MR recurrence was 14.5%. Repeat intervention rates were not reported.<sup>47</sup>

**Figures 2D to 2F** display the yearly pooled incidence of MR recurrence, reintervention, and their combination up to 5 years, on the basis of calculated weighted means with 95% CIs. Notably, M-TEER failure (**Figure 2F**) remained stable and  $<13\%$  in the first 3 years (on the basis of 17 studies with a total of 9,751 patients), followed by a substantial increase, up to a peak of 28%, at 5 years (on the basis of 5 studies with a total of 1,086 patients).

**FIGURE 3** Durability Data According to Mitral Regurgitation Etiology


In panels A and C: some confidence interval bars may not be visible because they are really close to the point estimates and therefore obscured by the corresponding circles; 4-year MRR data in PMR patients was absent, thus only the weighted means of MRR and M-TEER failure rates for SMR patients are shown.

(A) Weighted means with 95% CIs of MRR rates at different time points for PMR and SMR subgroups (the DerSimonian-Laird random-effects approach was applied to the estimates at 1, 2, and 5 years for PMR and to the estimates at 1 year for SMR; the rest of the estimates were calculated using the inverse variance fixed-effects model). (B) Weighted means with 95% CIs of RI rates at different time points for PMR and SMR subgroups (the DerSimonian-Laird random-effects approach was applied to the estimates at 1, 2, and 5 years for PMR and to the estimates at 1 year for SMR; the rest of the estimates were calculated using the inverse variance fixed-effects model). (C) Weighted means with 95% CIs of MRR and RI rates (mitral transcatheter edge-to-edge repair failure) at different time points for PMR and SMR subgroups (the DerSimonian-Laird random-effects approach was applied to the estimates at 1 and 2 years for PMR and to the estimates at 1 year for SMR; the rest of the estimates were calculated using the inverse variance fixed-effects model). Abbreviations as in Figure 2.

### WHAT AFFECTS M-TEER DURABILITY?

- MR etiology: Studies including both primary and secondary MR reported numerically higher 1-year rates of MR recurrence and reintervention among patients with primary MR compared with those with secondary MR (Figures 2A and 2B).<sup>12,16-18,24,27-31,35</sup> Furthermore, REPAIR (Registry of PASCAL for Mitral Regurgitation) and CLASP, respectively, at 2 and 3 years, reported MR recurrence and repeat intervention rates for the PASCAL device, displaying a trend for more events in primary MR patients, except for the 3-year MR recurrence rates in the CLASP registry, which were 6% in primary MR and 7% in secondary MR. In the REPAIR study, MR  $\leq 1+$  at both 1 and 2 years was more frequent after M-TEER for secondary than primary MR, and MR recurrence was more frequent with primary MR.<sup>35,39</sup> Five-year data from the EVEREST II High

Risk Study and 2 more recent single-center registries further confirm the numerically higher MR recurrence rates with primary MR patients, while repeat intervention rates appear more heterogeneous. Repeat intervention rates were higher for secondary MR in the EVEREST II High Risk Study and in the German registry.<sup>43-45</sup> Of note, in the EVEREST II, surgery was superior to M-TEER for the primary endpoint of freedom from death, mitral valve reintervention, or MR recurrence at 5 years for primary but not secondary MR.<sup>42</sup> In Figure 3, we summarize durability data according to MR etiology. We display the yearly pooled incidence (on the basis of weighted means) of MR recurrence, reintervention, and M-TEER failure up to 5 years for both primary and secondary MR. M-TEER failure seemed to be more frequent with primary MR (at 5 years, 40.7% vs 22.4%) (Figure 3C). The mechanism of MR recurrence

**TABLE 3 Treatment Strategies for M-TEER Failure**

| Treatment Strategy                                     | Preferred Failure Mechanism | APS, % <sup>a</sup> | 1-Year MRR, % <sup>a</sup> | Limitations                                                        |
|--------------------------------------------------------|-----------------------------|---------------------|----------------------------|--------------------------------------------------------------------|
| Redo M-TEER                                            | Structural ≈ functional     | 96.1                | 41.2                       | Technical complexity, increased MS risk, elevated MRR rates        |
| Transcatheter occluder devices                         | Structural >> functional    | 100 <sup>b</sup>    | NA                         | Limited applications, increased risk for hemolysis and dislocation |
| Direct and indirect transcatheter annuloplasty         | Functional >> structural    | 100 <sup>b</sup>    | NA                         | Limited applications and evidence, technical complexity            |
| Transcatheter electrosurgical techniques (ELASTA-Clip) | Structural ≈ functional     | 95.4                | 0                          | Elevated technical complexity                                      |
| MVS (repair > replacement)                             | Structural > functional     | 95.5                | 30 <sup>c</sup>            | High-risk procedure with a 30-d mortality up to 20%                |

Key features of the main strategies for managing M-TEER failure are described. <sup>a</sup>The highest rates reported in literature are presented (when available). <sup>b</sup>These rates are extracted for transcatheter occluder devices from a case series<sup>63</sup> and for direct and indirect transcatheter annuloplasty from single case reports.<sup>61,65</sup> <sup>c</sup>Refers to a rate recorded at a median follow-up of 163 days (Q1-Q3: 22-720 days).<sup>76</sup>

APS = acute procedural success; ELASTA-Clip = electrosurgical laceration and stabilization of MitraClip; MS = mitral stenosis; other abbreviations as in Table 1.

after M-TEER was mainly LLI and leaflet tearing for primary MR vs functional failure due to LV remodeling for secondary MR.<sup>12,48</sup> LLI typically occurred within the first 6 months after M-TEER, whereas functional failure emerged beyond the first year after the index procedure.<sup>37,49</sup>

- Anatomical complexity: The presence of large leaflet flail (flail gap ≥10 mm and/or flail width >15 mm), multisegmental prolapse (Barlow's disease), cleft, mitral valve orifice area <4 cm<sup>2</sup>, ≥2 independent jets, a commissural lesion with wide or multiple jets, leaflet mobility length <8 mm, severe calcification in the grasping area, and mitral annular calcification (MAC)<sup>20,50-53</sup> were independent predictors of reintervention at 3 years.<sup>20,52</sup> MAC was associated with higher rates of MR recurrence at 1 year (22.1% in patients with MAC vs 7.5% in those without MAC; *P* = 0.002) in a study of 260 patients undergoing M-TEER for primary MR with MAC.<sup>53</sup>
- Left atrial volume: Left atrial volume emerged as a predictor of MR recurrence in secondary MR at 1 year (HR per 10-mL increase: 1.14; 95% CI: 1.08-1.21; *P* < 0.001) in a German registry that included 685 patients with secondary MR undergoing M-TEER.<sup>12</sup>
- Device and procedural success and operator and center experience: Optimal procedural success with residual MR ≤1+ prevented MR recurrence and reintervention.<sup>10,12,44,52</sup> As such, higher operator and institutional experience improved procedural success and, therefore, M-TEER durability.<sup>54-56</sup>
- The MR proportionality framework could not identify patients at higher risk for MR recurrence at 1 year, although procedural success was highest

in patients with disproportionate secondary MR.<sup>26,57</sup>

- Furthermore, in 2 real-world registries totaling nearly 2,500 patients, device iterations that introduced separate leaflet grasping and an extended sizing matrix, improved procedural success but so far not M-TEER durability out to 3 years.<sup>35,52</sup>

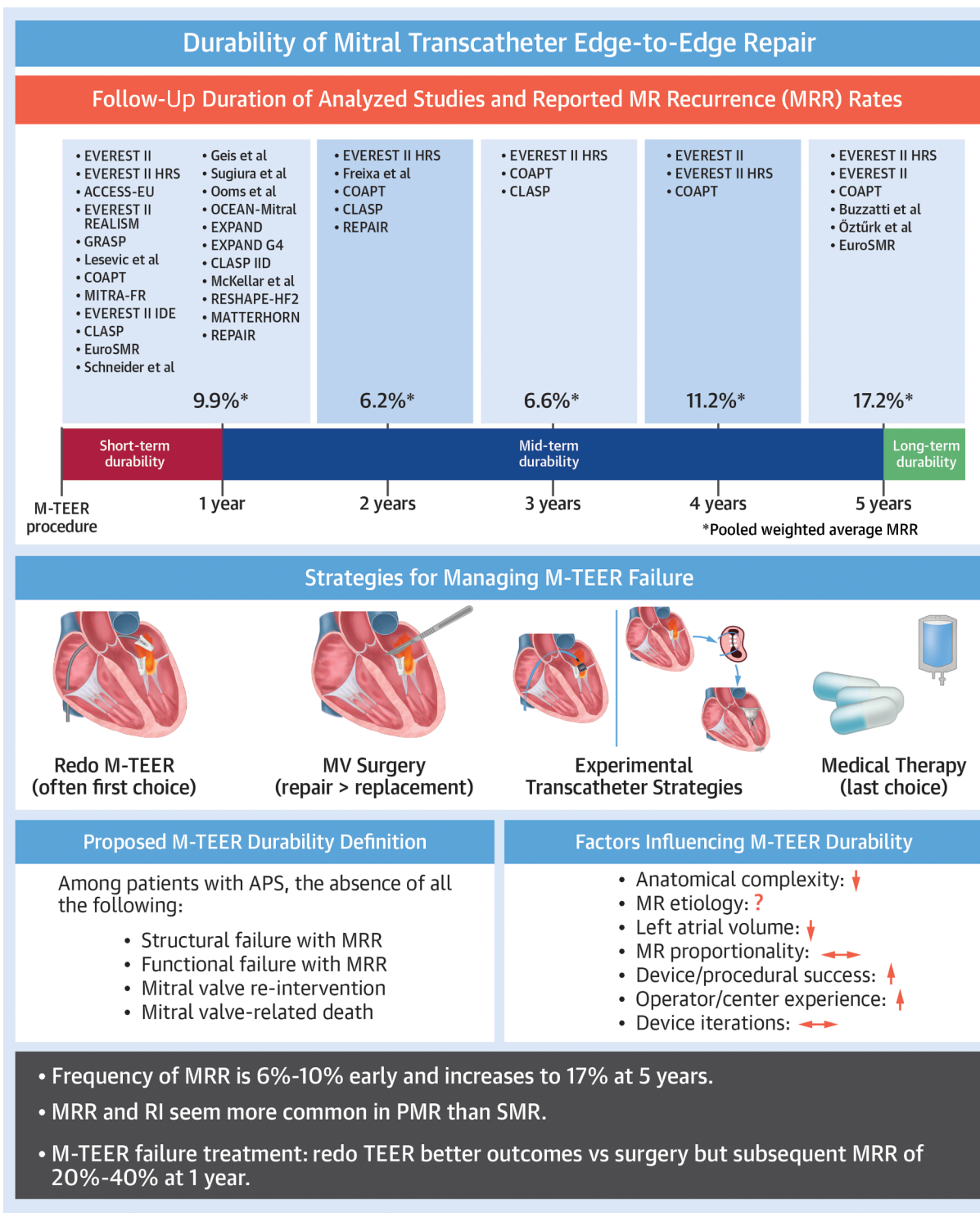
#### TREATMENT STRATEGIES FOR M-TEER FAILURE.

Strategies to manage M-TEER failure are summarized in Table 3.

Redo M-TEER is a feasible and safe therapeutic approach in selected patients, with APS up to 96%. Earlier reports that redo M-TEER would be less effective in the context of LLI (APS 84.6% without LLI vs 25% with LLI) were refuted in larger and more recent registries. Nonetheless, 1-year outcome data after redo M-TEER seem more reserved, with 1-year survival of about 60% to 80% and MR recurrence in up to 40%. The MR recurrence rate at 1 year was significantly lower after redo M-TEER than medical therapy only (23.1% vs 52.6%; *P* = 0.001).<sup>37,49,58-60</sup>

Elevated transmitral gradients, residual MR location (eg, commissural, between prior devices), and inability to grasp additional tissue may preclude redo M-TEER and trigger alternative transcatheter strategies. Occluder devices have been successfully used for treatment of MR due to commissural or inter-device jets and leaflet perforations but may be associated with hemolysis.<sup>61-64</sup> Direct and indirect transcatheter annuloplasty may be attempted in the context of MR recurrence and mitral annulus dilatation.<sup>61,65</sup> Electrosurgery techniques may be used to artificially create SLDA (electrosurgical laceration and stabilization of MitraClip), which is then

# CENTRAL ILLUSTRATION M-TEER Durability Over Time and Failure Management



Mariani A, et al. JACC Cardiovasc Interv. 2026;19(9):1057-1070.

Continued on the next page

followed by transcatheter mitral valve replacement.<sup>66-69</sup> Another strategy under development is to cut and remove the failing transcatheter edge-to-edge repair device with dedicated technology, followed by transcatheter mitral valve replacement.<sup>70,71</sup>

Mitral valve surgery is a safe and effective treatment of M-TEER failure in selected patients.<sup>72,73</sup> However, postoperative morbidity seems higher than after redo M-TEER, with incremental risks for bleeding, stroke, acute kidney injury, and permanent pacemaker implantation and reported 30-day mortality rates of 10% to 20%.<sup>58,74-77</sup> Mitral valve surgery outcomes seem impaired in secondary MR phenotypes, M-TEER failure after use of multiple devices, depressed LV function, and ischemic cardiomyopathy.<sup>72-74</sup> Repair techniques are associated with the best clinical outcomes and therefore should be preferred over mitral valve replacement. However, repair was applied in <15% of mitral surgery for M-TEER failure.<sup>72-74,78-80</sup>

We extracted the distribution of the 2 main mechanisms of M-TEER failure and MR recurrence among the available studies on reintervention strategies. Structural failure, especially LLI and SLDA, was more frequent than functional failure (61% vs 39%), as presented in [Supplemental Figure 1](#).<sup>37,49,58,59,68,74</sup>

## DISCUSSION

The salient findings of this narrative review on the durability of M-TEER can be summarized as follows ([Central Illustration](#)). 1) We looked at MR recurrence and reintervention after APS to ascertain M-TEER durability in the absence of uniform definitions of M-TEER durability or failure. 2) The estimated pooled rates of MR recurrence and reintervention varied

between 5% and 10% in the first months after the index procedure and then remained stable for the first 3 years ([Figures 2D and 2E](#)). At 5 years, the weighted rates of MR recurrence and reintervention increased to 17% and 9%, respectively ([Figures 2D and 2E](#)). 3) The estimated pooled rates of MR recurrence and reintervention are numerically higher for primary than secondary MR, and at 5 years, 41% of the primary MR patients experienced MR recurrence or reintervention ([Figure 3C](#)). 4) Redo transcatheter edge-to-edge repair for M-TEER failure was associated with 1-year MR recurrence rates between 20% and 40%. 5) Mitral valve replacement was the most common surgical technique for M-TEER failure.

The Mitral Valve Academic Research Consortium was an important initiative to disseminate uniform definitions for reporting on mitral valve interventions. More granularity in the definition of longer term M-TEER durability is warranted.

Our reported data may serve as a benchmark for M-TEER durability out to 5 years, and our observation that M-TEER effectiveness remained relatively stable up to 3 years (M-TEER failure <13%), with a meaningful decay afterward (M-TEER failure >25%), is legitimate and clinically meaningful. This review is a call for systematic longer follow-up to at least 5 years for prospective studies on M-TEER. However, in the 3 ongoing RCTs comparing M-TEER with surgery, the expected follow-up length remains heterogeneous. The duration of follow-up in REPAIR MR (Percutaneous MitraClip Device or Surgical Mitral Valve Repair in Patients With Primary Mitral Regurgitation Who Are Candidates for Surgery; [NCT04198870](#)) and MITRA-HR (Multicentre Study of MitraClip® Transcatheter Mitral Valve Repair in Patients With Severe Primary Mitral Regurgitation Eligible for High-Risk Surgery; [NCT03271762](#)) is 2 years, while in PRIMARY

### CENTRAL ILLUSTRATION Continued

The displayed mitral regurgitation recurrence (MRR) rates represent weighted means calculated by inverse variance weighting and a DerSimonian-Laird random-effects model.<sup>11,12,15-20,22-25,27-32,34,35,37,39,43,46</sup> ACCESS-EU = ACCESS-Europe: A Two-Phase Observational Study of the MitraClip System in Europe; APS = acute procedural success; CLASP = Edwards PASCAL Transcatheter Valve Repair System; CLASP IID = Edwards PASCAL Transcatheter Valve Repair System Pivotal Clinical Trial; COAPT = Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy for Heart Failure Patients With Functional Mitral Regurgitation; EuroSMR = European Registry of Transcatheter Repair for Secondary Mitral Regurgitation; EVEREST II = Endovascular Valve Edge-to-Edge Repair Study; EVEREST II HRS = EVEREST II High Risk Study; EVEREST II IDE = EVEREST II Investigational Device Exemption; EVEREST II REALISM = EVEREST II Real World Expanded Multicenter Study; EXPAND = A Contemporary, Prospective Study Evaluating Real-world Experience of Performance and Safety for the Next Generation of MitraClip® Devices; EXPAND G4 = A Post-Market Study Assessment of the Safety and Performance of the MitraClip G4 System; GRASP = Getting Reduction of Mitral Insufficiency by Percutaneous Clip Implantation; MATTERHORN = A Multicenter, Randomized, Controlled Study to Assess Mitral Valve Reconstruction for Advanced Insufficiency of Functional or Ischemic Origin; MITRA-FR = Multicentre Study of Percutaneous Mitral Valve Repair MitraClip Device in Patients With Severe Secondary Mitral Regurgitation; MR = mitral regurgitation; M-TEER = mitral transcatheter edge-to-edge repair; MV = mitral valve; OCEAN-Mitral = Optimized Catheter Valvular Intervention; PMR = primary mitral regurgitation; REPAIR = Registry of PASCAL for Mitral Regurgitation; RESHAPE-HF2 = Randomised Investigation of the MitraClip Device in Heart Failure: 2nd Trial in Patients With Clinically Significant Functional Mitral Regurgitation; RI = repeat intervention; SMR = secondary mitral regurgitation. TEER = transcatheter edge-to-edge repair.

(Percutaneous or Surgical Repair in Mitral Prolapse and Regurgitation for  $\geq 60$  Year-Olds; [NCT05051033](#)) it is 10 years.

M-TEER failure seemed more common with primary than secondary MR. The mechanism and timing of M-TEER failure varied between these 2 subgroups and was predominantly structural and within the first 6 months with primary MR (LLI, SLDA) vs functional and beyond the first year with secondary MR (LV and annular dilatation).

The treatment of M-TEER failure varied by the mechanism of failure and the underlying disease. Redo M-TEER was the dominant strategy for both structural and functional failure in a population that was characterized by advanced age, frailty, and comorbidities and thus at elevated operative risk. Surgery seemed a relatively high-risk procedure, with mortality rates up to 20% and a higher likelihood of mitral valve replacement than repair. Secondary MR phenotypes (more commonly functional failures), the use of multiple transcatheter edge-to-edge repair devices, depressed LV function, and ischemic cardiomyopathy were the main predictors for poor outcomes after surgery for M-TEER failure. Novel interventional techniques that include electrosurgery and an extended toolbox of transcatheter technologies and techniques (eg, chordal repair, annuloplasty, LV restoration) are under development or investigation and could be useful in patients at elevated operative risk when redo M-TEER is not technically feasible.

**STUDY LIMITATIONS.** MR recurrence was often not reported as such but deduced from the rates of patients with MR  $\geq 3+$  during follow-up. We could not differentiate residual MR  $>2+$  that was present after the index procedure and recurrent MR  $>2+$  at follow-up. Similarly, the cause for repeat intervention was underreported, and we could not differentiate reintervention for procedural failure vs reintervention for structural or functional failure. Of note, in the absence of individual patient-level data, some patients may be represented in more than 1 pooled estimate of MR recurrence and repeat intervention. The absence of transesophageal echocardiography assessment during follow-up may have limited the detection of structural or functional failure, particularly in patients with suboptimal procedural results.<sup>48</sup> The substantial heterogeneity of study designs, inclusion criteria, device iterations, APS

definitions, echocardiographic evaluations, and follow-up protocols may affect the weighted means of MR recurrence, reintervention, and their composite and should therefore be interpreted with caution and not as exact proportions. Finally, it should be noted that the primary and secondary MR pooled estimates were derived from a limited number of studies, with meaningful heterogeneity in terms of comorbidities, extent of LV remodeling, and mitral complexity.

## CONCLUSIONS

The incidence of M-TEER failure after a successful index procedure increases after 3 years and seems more pronounced with primary than secondary MR. More systematic, longer term follow-up after M-TEER is required.

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**KEY WORDS** device failure, durability, mitral regurgitation, MR recurrence, M-TEER, repeat intervention

**APPENDIX** For supplemental tables and a figure, please see the online version of this paper.



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