U.PORTO

MESTRADO INTEGRADO EM MEDICINA

Transcatheter Mitral Valve Repair in Severe Mitral Regurgitation: A Single-Center Observational Study

Mariana Isabel Pinto Soares

M

2026

Transcatheter Mitral Valve Repair in Severe Mitral Regurgitation: A Single-Center Observational Study

Dissertação de candidatura ao grau de Mestre em Medicina submetida ao Instituto de Ciências Biomédicas Abel Salazar da Universidade do Porto.

Estudante:

Mariana Isabel Pinto Soares

Mestrado Integrado em Medicina

Instituto de Ciências Biomédicas Abel Salazar, Universidade do Porto.

Endereço eletrónico: up202006472@up.pt

Orientador:

Dr. Bruno Miguel Fernandes Brochado

Assistente Hospitalar, Serviço de Cardiologia, Unidade Local de Saúde de Santo António, Porto, Portugal

Colaborador Externo do Instituto de Ciências Biomédicas Abel Salazar

Endereço eletrónico: brunobrochado.cardiologia@ulssa.min-saude.pt

Coorientador:

Professor Doutor André Miguel Coimbra Luz

Assistente Graduado, Serviço de Cardiologia, Unidade Local de Saúde de Santo António, Porto, Portugal

Professor Associado Convidado do Instituto de Ciências Biomédicas Abel Salazar

Endereço eletrónico: andreluz.cardiologia@chporto.min-saude.pt

Coorientadora:

Dra. Diana Alexandra Teixeira de Azevedo Ribeiro

Interna de Formação Específica, Serviço de Cardiologia, Unidade Local de Saúde de Santo António

Colaborador Externo do Instituto de Ciências Biomédicas Abel Salazar

Endereço eletrónico: u14896@ulssa.min-saude.pt

Porto, Junho de 2026

Estudante: Mariana Isabel Pinto Soares

Assinado por: Mariana Isabel Pinto Soares
Num. de Identificação: BI15728056
Data: 07-06-2026 12:48:40 +01:00

CHAVE MÓVEL

Orientador: Dr. Bruno Miguel Fernandes Brochado

Assinado por: **Bruno Miguel Fernandes Brochado**
Num. de Identificação: 12777804
Data: 2026.06.05 12:38:25+01'00'

Coorientador: Professor Doutor André Miguel Coimbra Luz

Assinado por: **André Miguel Coimbra Luz**
Num. de Identificação: 10564710
Data: 2026.06.07 12:37:55 +0100

Coorientadora: Dra. Diana Alexandra Teixeira de Azevedo Ribeiro

Assinado por: Diana Alexandra Teixeira de Azevedo Ribeiro
Identificação: BI15344318
Data: 2026-06-05 às 17:14:23

Porto, Junho de 2026

STATEMENT OF INTEGRITY

I hereby declare having conducted this academic work with integrity. I confirm that I have not used plagiarism or any form of undue use of information or falsification of results along the process leading to its elaboration.

Assinado por: Mariana Isabel Pinto Soares
Num. de Identificação: BI15728056
Data: 07-06-2026 12:51:51 +01:00

CHAVE MÓVEL

Student: Mariana Isabel Pinto Soares

DEDICATION

À minha Família, a minha raiz de amor, força e perseverança.

Aos meus Amigos, que são os ramos desta jornada e a encheram de luz, leveza e laços.

ACKNOWLEDGEMENTS

O percurso que culminou nesta dissertação começou muito antes da escolha do tema. Teve início no momento em que encontrei na Cardiologia uma área capaz de me cativar, graças àqueles que a souberam ensinar com rigor, entusiasmo e verdadeira vocação. Foi também assim que nasceu o meu interesse pela cardiologia de intervenção, área em que viria a desenvolver o presente trabalho, dedicado ao estudo da reparação percutânea na insuficiência mitral, que tive o privilégio de explorar e que abracei com genuíno interesse.

Ao meu orientador, Dr. Bruno Brochado, dirijo o meu mais sincero e profundo agradecimento. Por ter despertado em mim o fascínio por uma área tão estimulante quanto determinante no prognóstico dos doentes; pela proposta de um tema aliciante e desafiante; e pela dedicação incansável com que acompanhou cada etapa deste percurso. Esteve sempre disponível para esclarecer todas as minhas dúvidas, dedicou tempo e atenção a cada revisão e tornou possível que deste artigo resultasse algo de que muito me orgulho. A si agradeço não apenas o acompanhamento ao longo desta dissertação, mas todo o trajeto partilhado e tudo quanto aprendi consigo, não só enquanto aluna, mas também, e sobretudo, enquanto futura profissional.

Ao meu coorientador, Professor Doutor André Luz, expresso uma profunda gratidão e admiração. Foi consigo que tive o meu primeiro contacto com a Cardiologia, e foi também consigo que comecei a encarar esta especialidade com um brilho especial. Se cheguei a esta área e a este trabalho, foi, em grande parte, graças a si. O profissionalismo, a inteligência e a paixão com que partilha o seu conhecimento são, para mim, uma referência e uma inspiração.

À minha coorientadora, Dra. Diana Ribeiro, deixo um sentido agradecimento pela disponibilidade, pela atenção e por todo o apoio prestado ao longo deste trabalho, que em muito contribuíram para o resultado final.

Por fim, deixo um agradecimento a todos os doentes que aceitaram integrar este estudo. Sem eles, este trabalho não teria sido possível. É por eles, e para eles, que toda a investigação ganha sentido.

RESUMO

Introdução: A insuficiência mitral (IM) grave está associada a elevada morbilidade e mortalidade, particularmente em doentes idosos, frágeis ou com elevado risco cirúrgico. A reparação mitral transcateter *edge-to-edge* (M-TEER) com o sistema MitraClip emergiu como uma alternativa terapêutica menos invasiva para doentes selecionados com IM grave sintomática.

Objetivos: Descrever a experiência inicial de um centro português sem cirurgia cardíaca *on-site* com a técnica de M-TEER, priorizando a avaliação da segurança do procedimento e os resultados clínicos a curto prazo.

Métodos: Realizamos um estudo retrospetivo, observacional e unicêntrico de todos os doentes com insuficiência mitral grave sintomática de etiologia primária ou secundária, incluindo casos em que ambos os mecanismos coexistiam, avaliados por uma *Heart Team* multidisciplinar e submetidos a M-TEER com o sistema MitraClip entre novembro de 2024 e dezembro de 2025. Nos doentes com IM primária, o procedimento foi considerado em indivíduos com alto ou proibitivo risco cirúrgico. Nos doentes com IM secundária, a elegibilidade exigiu sintomas persistentes apesar de terapêutica médica otimizada (TMO) e, quando indicada, terapêutica de ressincronização cardíaca (CRT). Foram extraídos dados relativos às características demográficas dos doentes, estado clínico, parâmetros laboratoriais, risco cirúrgico, características ecocardiográficas, cateterismo cardíaco direito pré-procedimento, resultados do procedimento e follow-up clínico e ecocardiográfico. O *endpoint* primário de segurança foi a ocorrência de eventos adversos major durante o internamento. O *endpoint* primário de eficácia foi o internamento por insuficiência cardíaca durante os primeiros 6 meses de *follow-up*.

Resultados: Foram incluídos 11 doentes (45,5% com IM funcional, 36,4% com IM degenerativa e 18,2% de etiologia mista). A idade média foi de 75,6 ± 9,4 anos. As comorbilidades mais frequentes da amostra foram hipertensão arterial (72,7%), dislipidemia (63,6%) e fibrilhação auricular (54,5%). Todos os doentes apresentavam insuficiência cardíaca sintomática; 63,6% encontravam-se em classe funcional NYHA III/IV e 72,7% tinham tido pelo menos um internamento por insuficiência cardíaca no último ano. 72,7% dos doentes apresentaram uma anatomia mitral complexa. O sucesso do dispositivo foi alcançado em todos os casos, enquanto o sucesso do procedimento ocorreu em 90,9% dos doentes. Não ocorreram eventos adversos major durante o internamento. IM residual ≤2+ à alta hospitalar foi observada em 90,9% dos doentes, sem casos de IM grave aos 6 meses. Verificou-se melhoria da classe funcional NYHA em 72,7% dos doentes e ausência de internamentos por insuficiência cardíaca durante o *follow-up.*

Conclusões: Nesta experiência inicial, a M-TEER com MitraClip demonstrou ser exequível e segura num centro sem cirurgia cardíaca *on-site*, associando-se a uma elevada taxa de sucesso do procedimento, redução sustentada da insuficiência mitral e resultados clínicos encorajadores a curto prazo. Estudos prospetivos com maior dimensão amostral e maior período de seguimento serão necessários para confirmar estes resultados.

Palavras-Chave: Insuficiência mitral; MitraClip; Reparação mitral transcateter *edge-to-edge* (M-TEER); Reparação transcateter *edge-to-edge* (TEER); insuficiência cardíaca.

ABSTRACT

Background: Severe mitral regurgitation (MR) is associated with substantial morbidity and mortality, particularly in elderly, frail, or high surgical-risk patients. Mitral transcatheter edge-to-edge repair (M-TEER) using the MitraClip system has emerged as a less invasive therapeutic alternative for selected patients with symptomatic severe MR.

Objectives: Describe the initial experience of a Portuguese center without on-site cardiac surgery performing M-TEER, focusing on procedural safety and short-term clinical outcomes.

Methods: We conducted a retrospective, observational, single-center study including all patients with symptomatic severe MR of primary or secondary etiology, including cases where both mechanisms coexisted, evaluated by a multidisciplinary Heart Team and who underwent M-TEER with the MitraClip system between November 2024 and December 2025. In patients with primary MR, the procedure was considered in those deemed at high or prohibitive surgical risk. In patients with secondary MR, eligibility required persistent symptoms despite optimized guideline-directed medical therapy (GDMT) and, when indicated, cardiac resynchronization therapy (CRT). Data included patients baseline demographics characteristics, clinical status, laboratory parameters, surgical risk, echocardiographic characteristics, preprocedural right heart catheterization, procedural outcomes and clinical and echocardiographic follow-up. The primary safety endpoint was the occurrence of major adverse events (MAEs) during hospitalization. The primary effectiveness endpoint was hospitalization for heart failure within 6 months of follow-up.

Results: A total of 11 patients were enrolled in the study (45,4% functional MR, 36,4% degenerative MR and 18.2% mixed etiology). Mean age was 75.6 ± 9.4 years. The most prevalent comorbidities were arterial hypertension (72.7%), dyslipidemia (63.6%), and atrial fibrillation (54.5%). All patients had symptomatic heart failure, with 63.6% in NYHA functional class III/IV and 72.7% having had a prior heart failure hospitalization within the previous year. Complex mitral valve anatomy was present in 72.7% of patients. Device success was achieved in all procedures, whereas procedural success was achieved in 90.9% of cases. No MAEs occurred during hospitalization. Residual MR ≤2+ at discharge was observed in 90.9% of patients, with no cases of severe MR at 6 months. Improvement in NYHA functional class was observed in 72.7% of patients, and no heart failure hospitalizations occurred during follow-up.

Conclusions: In this initial experience, M-TEER with the MitraClip system was feasible and safe in a center without on-site cardiac surgery, demonstrating high procedural success, sustained

MR reduction, and encouraging early short-term clinical outcomes. Larger prospective studies with longer follow-up are warranted to confirm these findings.

Keywords: Mitral Valve Regurgitation; MitraClip; Mitral transcatheter edge-to-edge repair (M-TEER); Transcatheter edge-to-edge repair (TEER); Heart Failure.

LIST OF ABBREVIATIONS

ACEi/ARAII: angiotensin-converting enzyme inhibitors/angiotensin II receptor antagonists

ARNI: Angiotensin Receptor-Neprilysin Inhibitors

BARC: Bleeding Academic Research Consortium

CABG: Coronary Artery Bypass Grafting

CAD: Coronary Artery Disease

CE: *Conformité Européenne*

CI: Cardiac Index

CO: Cardiac Output

COPD: Chronic Obstructive Pulmonary Disease

CRT: Cardiac Resynchronization Therapy

dPAP: Diastolic Pulmonary Artery Pressure

EACTS: European Association for Cardio-Thoracic Surgery

eGFR: Estimated Glomerular Filtration Rate

EROA: Effective Regurgitant Orifice Area

ESC: European Society of Cardiology

EuroSCORE II: European System for Cardiac Operative Risk Evaluation II

FDA: Food and Drug Administration

GDMT: Guideline-Directed Medical Therapy

HF: Heart Failure

LOE: Level Of Evidence

LVEDD: Left Ventricular End-Diastolic Diameter

LVEDV: Left Ventricular End-Diastolic Volume

LVEF: Left Ventricular Ejection Fraction

LVESD: Left Ventricular End-Systolic Diameter

LVESV: Left Ventricular End-Systolic Volume

MAEs: Major Adverse Events

mPAP: Mean Pulmonary Artery Pressure

MR: Mitral Regurgitation

MRA: Mineralocorticoid Receptor Antagonists

M-TEER: Mitral Transcatheter Edge-to-Edge Repair

MVA: Mitral Valve Area

MVARC: Mitral Valve Academic Research Consortium

NT-proBNP: N-terminal pro-B-type Natriuretic Peptide

NYHA: New York Heart Association

PAWP: Pulmonary Artery Wedge Pressure

PCI: Percutaneous Coronary Intervention

PVR: Pulmonary Vascular Resistance

RegVol: Regurgitant Volume

RVEDP: Right Ventricular End-Diastolic Pressure

SD: Standard Deviation

SGLT2i: Sodium-Glucose Cotransporter-2 Inhibitors

SMR: Secondary Mitral Regurgitation

sPAP: Systolic Pulmonary Artery Pressure

STS: Society of Thoracic Surgeons

TAPSE: Tricuspid Annular Plane Systolic Excursion

TAVI: Transcatheter Aortic Valve Implantation

ULSSA: Unidade Local de Saúde de Santo António

VCW (2C): Vena Contracta Width (2-Chamber View)

VCW (3C): Vena Contracta Width (3-Chamber View)

TABLE OF CONTENTS

ACKNOWLEDGEMENTS i
RESUMO ii
ABSTRACT iv
LIST OF ABBREVIATIONS vi
LIST OF TABLES ix
LIST OF FIGURES x
INTRODUCTION 1
METHODS 3
Study Design and Population 3
Data Collection and Study Variables 4
Study Endpoints 5
Statistical Analysis 6
Ethical Approval 7
RESULTS 7
Study Population and Baseline Characteristics 7
Baseline Echocardiographic Characteristics 7
Hemodynamic Assessment 8
Procedural Outcomes 8
Clinical and Echocardiographic Follow-Up 9
DISCUSSION 9
CONCLUSION 12
APPENDIX 13
REFERENCES 23

LIST OF TABLES

Table I. Study Baseline Demographic Characteristics

Table II. Study Baseline Echocardiographic Characteristics

Table III. Preprocedural Right Heart Catheterization Findings

Table IV. Procedural Outcomes

Table V. Clinical and Echocardiographic Follow-Up

LIST OF FIGURES

Figure 1. Distribution of NYHA functional class at baseline and 6-month follow-up

Figure 2. Distribution of mitral regurgitation severity at baseline, discharge, and 6-month follow-up after TEER

INTRODUCTION

Mitral valve insufficiency, or mitral regurgitation (MR) is one of the most prevalent valvular heart diseases, affecting approximately 10% of individuals over 75 years of age.[1] Chronic severe MR leads to persistent volume overload of the left atrium and left ventricle, resulting in progressive chamber dilation and left ventricular dysfunction.[2,3,4] This pathophysiological cascade ultimately leads to pulmonary congestion, symptomatic heart failure, reduced quality of life, and increased mortality if left untreated.[3]

MR can be classified as acute or chronic, and by etiology into primary (degenerative) and secondary (functional) forms.[2,3] Acute MR, usually due to papillary muscle rupture, chordal rupture, or infective endocarditis, often causes acute pulmonary edema and requires urgent surgical intervention.[3,4] Chronic MR progresses slowly, initially compensated but eventually decompensates, leading to heart failure.[3,4] Primary MR results from intrinsic valve lesions (e.g., leaflet prolapse, rheumatic disease), while secondary MR develops from left ventricular or atrial remodeling that prevents adequate leaflet coaptation despite structurally normal leaflets.[3] This distinction is clinically relevant, as primary MR is often curable with surgery, whereas secondary MR reflects myocardial disease with a different therapeutic profile.[3,4]

Medical therapy, including guideline-directed treatment for heart failure, may alleviate symptoms but may not completely prevent disease progression or correct the regurgitation.[3] Surgical mitral valve repair or replacement remains the gold standard, particularly in primary MR, with excellent long-term outcomes when performed in appropriate candidates and experienced centers.[3,5] However, many patients with severe MR, especially elderly, frail, or multimorbid individuals, are deemed inoperable or at high surgical risk.[5] The situation is particularly challenging in secondary MR, where surgical results are less favorable and recurrence rates remain high.[3,6] Consequently, a large proportion of patients with severe MR remain undertreated, with poor outcomes under medical therapy alone.[3]

To address this therapeutic gap, transcatheter mitral valve therapies have been developed, of which the most widely adopted is mitral valve transcatheter edge-to-edge repair (M-TEER) using the Mitraclip device, which replicates the Alfieri surgical technique by grasping and joining the mitral leaflets to reduce regurgitation.[3,7] The first-in-human procedure was performed in 2003, with *Conformité Européenne* (CE) marking approval in Europe in 2008, followed by United States Food and Drug Administration (FDA) approval for primary MR in 2013 and for secondary MR in 2019.[5] Since then, more than 200,000 patients worldwide have undergone M-TEER.[8]

Early evidence from the EVEREST II trial (2011), conducted predominantly in patients with primary MR, showed that M-TEER was less effective than surgery in achieving complete MR reduction but was associated with fewer peri-procedural complications, with no significant differences in mortality, supporting its use in high-risk patients.[5,9] In secondary MR, initial randomized trials yielded divergent results, with the MITRA-FR trial (2018) showing no significant benefit over guideline-directed medical therapy (GDMT), whereas the COAPT trial (2018) demonstrated significant reductions in heart failure hospitalizations and mortality in carefully selected patients, highlighting the critical importance of patient selection.[10,11] The long-term results (5-year follow-up) from the COAPT trial confirmed that M-TEER reduced heart failure hospitalizations and, especially, all-cause mortality compared with GDMT alone.[12] More recently, the RESHAPE-HF2 trial (2024) extended this evidence to patients with moderate-to-severe secondary MR who remained symptomatic despite optimized medical therapy, demonstrating reductions in recurrent heart failure hospitalizations and cardiovascular events, together with improved health status, compared with medical therapy alone.[13] Subsequently, the MATTERHORN trial (2024) provided a direct comparison between M-TEER and surgery in patients with secondary MR, demonstrating non-inferiority of M-TEER for major clinical outcomes (all-cause mortality, heart failure hospitalization, and mitral valve reintervention), with a more favorable safety profile but a higher rate of residual or recurrent MR.[14] Accordingly, the 2025 European Society of Cardiology (ESC) guidelines upgraded the recommendation for M-TEER in symptomatic patients with severe primary MR who are at high surgical risk (class IIa, level of evidence [LOE] B) and, in secondary MR, M-TEER is now highly recommended in carefully selected patients who remain symptomatic despite optimized GDMT, emphasizing the importance of a stepwise and multidisciplinary approach to patient selection (class I, LOE A).[3]

In this context, the present observational study aims to describe the initial experience with MitraClip implantation at Unidade Local de Saúde de Santo António (ULSSA), the first Portuguese center without on-site cardiac surgery to perform M-TEER, through a retrospective analysis focusing on procedural safety and short-term outcomes. Grounded in real-world clinical practice, this work extends beyond a purely academic contribution to the expanding international literature on transcatheter mitral repair. It is designed to generate evidence that may support clinical and institutional decision-making regarding the long-term integration, development, and expansion of TEER at ULSSA, with potential implications for the strategic evolution of both the department and the hospital. In doing so, it may also provide valuable insights into the role of M-TEER in centers without on-site cardiac surgery and contribute to the development of similar programs in comparable healthcare settings.

METHODS

Study Design and Population

This is a retrospective, observational, single-center cohort study evaluating the use of M-TEER with the MitraClip system at ULSSA, between November 2024 and December 2025.

Adult patients (≥18 years) with symptomatic severe mitral regurgitation, defined according to an integrative echocardiographic assessment (including qualitative, semi-quantitative, and quantitative criteria) as recommended by the ESC and European Association for Cardio-Thoracic Surgery (EACTS) guidelines, were considered for inclusion.[3]

All patients were evaluated by a multidisciplinary Heart Team, including a heart failure specialist, interventional cardiologist, and cardiac imaging specialist. M-TEER was considered in patients who remained symptomatic despite optimized GDMT and, when indicated, cardiac resynchronization therapy (CRT), particularly those considered unsuitable for surgery due to high or prohibitive surgical risk.

Patients were stratified according to MR etiology into primary MR and secondary MR, the latter further classified into ventricular or atrial secondary MR based on echocardiographic and clinical criteria.[3] In some patients, primary and secondary MR mechanisms coexisted and were classified as mixed MR.[15] In cases of mixed MR management decisions were individualized accordingly.

In patients with primary MR, M-TEER was considered in symptomatic individuals with severe MR who were deemed at high or prohibitive surgical risk, in accordance with ESC recommendations (Class IIa).[3]

In patients with secondary MR, eligibility for M-TEER required persistent symptoms despite optimized GDMT and assessment of clinical and echocardiographic characteristics, including those used in landmark trials such as the COAPT trial.[3,10] These included left ventricular ejection fraction between 20% and 50%, left ventricular end-systolic diameter ≤70 mm, evidence of elevated natriuretic peptides or prior heart failure hospitalization, and absence of advanced heart failure or indications for myocardial revascularization.[3] In this context, M-TEER was performed in accordance with current guideline-supported indications, with Class I LOE A recommendation in selected patients with ventricular secondary MR fulfilling COAPT-like criteria, and Class IIb LOE B recommendation in other clinical scenarios, including atrial secondary MR or patients not meeting strict selection criteria.[3,16]

Final eligibility for M-TEER was determined by the Heart Team based on an integrated assessment of clinical status, MR severity, underlying etiology, response to optimized GDMT, and overall procedural suitability, reflecting an individualized patient-centered approach rather than strict predefined criteria.

Patients were excluded if they had a life expectancy of less than one year due to non-cardiac comorbidities, active infective endocarditis, unsuitable mitral valve anatomy precluding device implantation, hemodynamic instability not amenable to percutaneous intervention, or had an independent indication for cardiac surgery due to other cardiac conditions (e.g., significant coronary artery disease requiring revascularization).[3,5]

Data Collection and Study Variables

Clinical, laboratory, imaging, and procedural data were retrospectively collected from the institution's electronic medical records.

Baseline characteristics included demographic data (age, weight, height), cardiovascular risk factors, and comorbidities, namely coronary artery disease, dyslipidemia, smoking status, diabetes mellitus, arterial hypertension, prior myocardial infarction, previous percutaneous coronary intervention (PCI) or coronary artery bypass grafting (CABG), peripheral arterial disease, prior stroke, chronic obstructive pulmonary disease (COPD), atrial fibrillation, chronic kidney disease requiring dialysis, and prior cardiac implantable devices (CRT, implantable cardioverter-defibrillator, or conventional pacemaker). Previous structural cardiac interventions, including transcatheter aortic valve implantation (TAVI), aortic surgery, or prior mitral valve procedures, were also recorded.

Clinical status was assessed using the New York Heart Association (NYHA) functional class and the number of hospitalizations for heart failure in the previous year. The presence of contraindications to heart transplantation and other significant valvular diseases (defined as grade ≥2+) was also documented.

Laboratory parameters included N-terminal pro–B-type natriuretic peptide (NT-proBNP), estimated glomerular filtration rate (eGFR), hemoglobin, leukocyte count, platelet count, international normalized ratio (INR), and serum creatinine. Baseline pharmacological therapy was recorded, including angiotensin-converting enzyme inhibitors (ACEi), angiotensin II receptor antagonists (ARAII), angiotensin receptor-neprilysin inhibitors (ARNI), beta-blockers, mineralocorticoid receptor antagonists (MRA), sodium-glucose cotransporter-2 inhibitors (SGLT2i), digoxin, ivabradine, nitrates, and antithrombotic drugs.

Surgical risk was assessed using the Society of Thoracic Surgeons (STS) score and the European System for Cardiac Operative Risk Evaluation II (EuroSCORE II), which estimate operative mortality risk in cardiac surgery. Additionally, the EuroSMR score, an artificial intelligence–based tool predicting 1-year mortality after M-TEER, was calculated for all patients.[17,18]

MR severity was assessed through an integrative echocardiographic evaluation in accordance with current guideline recommendations and subsequently reported using a 0-4+ grading scale: 0 (none or trace), 1+ (mild), 2+ (mild to moderate), 3+ (moderate to severe), and 4+ (severe).[3,18] Structural and functional parameters included left ventricular end-diastolic and end-systolic diameters (LVEDD, LVESD), left ventricular end-diastolic and end-systolic volumes (LVEDV, LVESV), left atrial volume, and left ventricular ejection fraction (LVEF). Right ventricular function and pulmonary pressures were assessed using tricuspid annular plane systolic excursion (TAPSE) and systolic pulmonary artery pressure (sPAP).

Detailed mitral valve assessment included effective regurgitant orifice area (EROA), regurgitant volume (RegVol), mitral valve area (3D planimetry), annular dimensions (intercommissural and anteroposterior diameters), coaptation length and depth, leaflet morphology (fibrosis and calcification), presence of flail and flail gap, tenting area, and jet characteristics (location, number of jets, and vena contracta in two- and three-dimensional assessment). Tricuspid regurgitation was equally graded from 0 (none) to 4+ (severe).

Pre-procedural invasive hemodynamic data obtained from right heart catheterization included systolic, diastolic, and mean pulmonary artery pressures, pulmonary artery wedge pressure (PAWP), right ventricular end-diastolic pressure (RVEDP), cardiac output (CO), cardiac index (CI), and pulmonary vascular resistance (PVR).

Procedural data included post-procedural mitral valve area, transmitral gradient (pre- and post-procedure), and residual MR severity at discharge.

Procedural and in-hospital complications were systematically assessed, including cardiovascular mortality, stroke, myocardial infarction, mitral valve reintervention, device-related complications, vascular complications, in-hospital bleeding (classified according to Bleeding Academic Research Consortium [BARC] criteria), and other procedure-related complications, such as pericardial effusion and air embolism.[19]

Study Endpoints

Study assessments were performed at baseline, hospital discharge, and at 6-month follow-up.

The primary effectiveness endpoint was hospitalization for heart failure within 6 months of follow-up.

The primary safety endpoint was defined as the occurrence of major adverse events (MAEs) from the procedure until hospital discharge, according to adapted Mitral Valve Academic Research Consortium (MVARC) criteria.[20] MAEs included all-cause death, stroke, life-threatening or major bleeding, major vascular complications, major cardiac structural complications, stage 2 or 3 acute kidney injury, myocardial infarction or coronary ischemia requiring PCI or CABG, severe hypotension or heart failure requiring advanced hemodynamic or respiratory support, and device-related dysfunction requiring surgical or percutaneous reintervention.[20]

Secondary effectiveness endpoints included: (i) reduction in MR severity at discharge compared with baseline, as assessed by echocardiography; (ii) reduction in MR severity at 6-month follow-up compared with baseline, as assessed by echocardiography; (iii) improvement in NYHA functional class at 6-month follow-up; and (iv) changes in echocardiographic parameters at 6-month follow-up, including LVEF, left ventricular dimensions and volumes, left atrial volume, sPAP and TAPSE.

Device success was defined as successful delivery and deployment of the device in the intended position, with adequate leaflet grasping and retrieval of the delivery system at the time of patient exit from the cardiac catheterization laboratory.[18]

Procedural success was defined as proper placement of the device without procedural mortality or the need for surgical or percutaneous intervention before hospital discharge, and with effective reduction of MR, defined as a reduction to MR grade ≤2+ at discharge.[18]

Clinical success was defined as procedural success without MAEs and with sustained clinical improvement at follow-up, including improvement in NYHA functional class and absence of heart failure hospitalization at 6 months.[18]

Statistical Analysis

Statistical analysis was performed using IBM SPSS Statistics, version 31.0 (IBM Corp., Armonk, NY, USA). Categorical variables were expressed as frequencies and percentages (%), and continuous variables as mean ± standard deviation (SD).

Given the small sample size and the descriptive nature of the study, no formal hypothesis testing was performed.

Ethical Approval

This study was conducted in accordance with the principles outlined in the Declaration of Helsinki and was approved by the institutional Ethics Committee (protocol number 2025-254(212-CAC/212-CE)). Written informed consent was obtained from all patients.

RESULTS

Study Population and Baseline Characteristics

Between November 2024 and December 2025, 11 patients underwent M-TEER with the MitraClip system at ULSSA.

Mean age was 75.55 ± 9.35 years, and 54.5% of patients were female. Baseline demographic characteristics are summarized in Table I.

The study population had a high burden of cardiovascular comorbidities, including arterial hypertension (72.7%), dyslipidemia (63.6%), atrial fibrillation (54.5%), and coronary artery disease (45.5%). Renal dysfunction was common, with an estimated glomerular filtration rate below 30 mL/min in 45.5% of patients.

Most patients were highly symptomatic at baseline, with almost two-thirds in NYHA functional class III or IV. Heart failure hospitalization within the previous year occurred in 72.7% of patients, and mean NT-proBNP level was 2829.20 ± 2486.67 pg/mL.

Before M-TEER, all patients were evaluated by the local Heart Team, and GDMT was optimized as clinically tolerated. Beta-blockers were prescribed in all patients, whereas ARNI, ACEi/ARAII, MRA and SGLT2i were used in 9.1%, 36.4%, 27.3%, and 63.6% of patients, respectively. Diuretics were prescribed in 90.9% of patients.

Mean EuroSCORE II and STS predicted operative mortality were 3.55 ± 1.99% and 3.58 ± 3.63%, respectively, consistent with a low-to-intermediate surgical risk profile.[21,22] Mean EuroSMR score was 49.35 ± 9.10, corresponding to an estimated 1-year mortality risk of approximately 26%.[23]

Baseline Echocardiographic Characteristics

Baseline echocardiographic characteristics are summarized in Table II.

Severe mitral regurgitation (grade 4+) was present in all patients at baseline. Secondary MR was the predominant etiology (45.5%), whereas primary and mixed etiologies accounted for 36.4% and 18.2% of cases, respectively.

Mean LVEF was 53.36 ± 11.77%, and mean sPAP was 51.27 ± 20.49 mmHg. Among patients with secondary MR, mean LVEF was 55.20 ± 13.66%, with values of 41.50 ± 10.61% in ventricular secondary MR and 64.33 ± 2.98% in atrial secondary MR. Concomitant tricuspid regurgitation of at least moderate severity (≥2+) was present in 54.5% of patients.

A high degree of mitral valve complexity was identified in 72.7% of patients. Multiple regurgitant jets were identified in 45.5% of cases, and leaflet calcification was present in 45.5% of patients.

Pulmonary vein flow reversal was present in 54.5% of patients. Mean EROA and RegVol were 41.80 ± 9.30 mm^2 and 61.33 ± 17.65 mL, respectively.

Echocardiographic measurements revealed a mean left atrial volume of 132.71 ± 49.48 mL, a mean LVEDV of 130.60 ± 52.04 mL, and a mean LVESD of 40.74 ± 12.11 mm.

Hemodynamic Assessment

Preprocedural right heart catheterization findings are summarized in Table III. Hemodynamic assessment was available for most patients, although some parameters were not available in all cases.

Mean pulmonary artery pressure was 33.63 ± 12.65 mmHg, whereas mean PAWP was 19.62 ± 10.07 mmHg.

Mean CO and CI were 3.86 ± 0.59 L/min and 2.24 ± 0.33 L/min/m^2, respectively. Mean PVR was 3.67 ± 2.12 Wood units.

Procedural Outcomes

Procedural outcomes are summarized in Table IV.

Device success was achieved in all patients (100%), whereas procedural and clinical success were achieved in 90.9% of cases. One patient did not meet procedural success criteria due to persistence of grade 3+ residual MR at discharge in spite of successful device implantation.

One device was implanted in 45.5% of patients, two devices in 45.5%, and three devices in one patient (9.1%), resulting in a mean of 1.64 ± 0.67 clips per patient.

Mitral regurgitation severity was markedly reduced following the procedure. At hospital discharge, 90.9% of patients presented residual MR grade ≤2+, including 18.2% with grade 1+ and 72.7% with grade 2+ MR. One patient (9.1%) remained with grade 3+ residual MR.

Mean transmitral gradient increased from 2.10 ± 0.77 mmHg to 2.73 ± 1.10 mmHg following M-TEER and mean mitral valve area decreased from 5.44 ± 1.75 cm^2 to 2.75 ± 0.76 cm^2.

Mean length of hospital stay was 3.18 ± 3.92 days, and all patients were discharged home.

During hospitalization, one device-related complication was observed, consisting of single leaflet device attachment due to partial leaflet detachment not requiring specific intervention. No major adverse events, cardiovascular mortality, stroke, myocardial infarction, vascular complications, or mitral valve reintervention were observed.

Clinical and Echocardiographic Follow-Up

Clinical and echocardiographic follow-up findings are summarized in Table V.

No hospitalizations for heart failure were observed during the 6-month follow-up period.

Improvement in NYHA functional class was observed in 72.7% of patients. The proportion of patients in NYHA functional class III/IV decreased from 63.6% at baseline to 9.1% at follow-up (Figure 1).

Sustained reduction in mitral regurgitation severity was observed throughout follow-up. At discharge, 90.9% of patients presented residual MR grade ≤2+, and all patients achieved at least a one-grade reduction in MR severity compared with baseline. At 6-month follow-up, no patients presented severe (grade 4+) mitral regurgitation, with most patients presenting MR grade 1+ or 2+ (Figure 2).

Available follow-up echocardiographic data demonstrated a numerical reduction in left atrial volume and sPAP in the available examinations, although no formal statistical comparisons were performed due to the limited sample size and incomplete follow-up echocardiographic data.

DISCUSSION

In this initial single-center experience, M-TEER with the MitraClip system was technically feasible in all the 11 patients. Device success was achieved in 100% of cases and procedural success in more than 90%, and no MAEs occurred during hospitalization. The single device-related event consisted of partial leaflet detachment resulting in single-leaflet device attachment. This event did not fulfil MVARC criteria for a MAEs, did not compromise the hemodynamic result, and did not require reintervention during follow-up.[20] These findings compare superiorly with the percutaneous arm of EVEREST II, in which the 30-day MAEs rate was 15% with a first-generation MitraClip and at a time when operator experience was still being accumulated.[9] They are also in

line with the safety profile reported in more recent series.[10,13,14] COAPT reported 96.6% freedom from device-related complications at 12 months, RESHAPE-HF2 reported periprocedural adverse events in only 1.6% of patients in the device group, MATTERHORN demonstrated substantially fewer adverse events with M-TEER than with surgical repair (14.9% vs 54.8% at 30 days), and the MiCLASP post-market study reported a 30-day composite MAEs rate of 6.8% with an alternative TEER system.[10,13,14,18] The small size of the cohort makes the confidence interval around a zero event rate wide, so this observation should be regarded as a hypothesis-generating signal rather than as evidence of an established safety threshold. Even so, the fact that a high-complexity anatomical profile (multiple jets in 45.5%, leaflet calcification in 45.5%, and complex valve morphology in 72.7%) was managed without major complications suggests that careful Heart Team preparation and patient selection have surpassed the hypothetical drawbacks of initial experience and absence of on-site surgical back-up.

Mitral regurgitation was substantially reduced after the procedure. All patients achieved at least a one-grade reduction, 90.9% reached residual MR ≤2+ at discharge and, of these, all maintained residual MR ≤2+ at 6 months. These figures are consistent with the benchmarks reported in landmark trials and contemporary real-world series, in which MR ≤2+ at discharge is achieved in 91 to 98% of treated patients.[10,11,13,17,18] In the single patient with persistent grade 3+ residual MR, the procedure was limited by an increase in the transmitral gradient after the first clip, which precluded the placement of additional devices without inducing significative mitral restriction. This trade-off between MR reduction and iatrogenic stenosis is a well-recognized constraint of the technique.[20] Across the cohort, post-procedural transmitral gradient (2.73 ± 1.10 mmHg) and mitral valve area (2.75 ± 0.76 cm^2) remained within the safe hemodynamic range, including in the patients who received multiple devices, indicating that effective MR reduction was achieved without compromising mitral valve hemodynamics.[20]

No heart failure hospitalization occurred during the 6-month follow-up period, and 72.7% of patients improved by at least one NYHA functional class. The proportion of patients in class III or IV decreased from 63.6% at baseline to less than 10% at follow-up. These short-term clinical observations are encouraging but must be interpreted with caution. The landmark randomized trials in M-TEER, including EVEREST II, MITRA-FR, MATTERHORN, COAPT, and RESHAPE-HF2, were all designed with primary effectiveness endpoints assessed at 12 months or beyond, extending to 24 months in COAPT and RESHAPE-HF2.[9,10,11,13,14] In COAPT and RESHAPE-HF2, which demonstrated a significant reduction in heart failure hospitalizations, the difference between the device and control groups grew progressively throughout the 24 months of follow-up, highlighting the

limitations of a 6-month observation window.[10,13] Our primary effectiveness endpoint, hospitalization for heart failure within 6 months of follow-up, therefore captures early symptomatic response but is inherently limited for drawing conclusions about long-term hospitalization burden. Regarding procedural safety, our primary safety endpoint, defined as MAEs from the procedure until hospital discharge, reflected the immediate periprocedural risks of the intervention. This window is shorter than the 30-day periprocedural safety assessment used in some M-TEER trials, which may result in an underestimation of early post-discharge complications.[9,14,18] The absence of a control group introduces an additional layer of uncertainty, limiting the ability to establish a causal relationship between M-TEER and the observed clinical improvement.

Despite these limitations, the favorable early clinical trajectory observed in our cohort highlights the importance of appropriate patient selection for M-TEER. This concept was reinforced by the contrasting results of the MITRA-FR and COAPT trials, which led to the development of the proportionate–disproportionate MR framework.[24] According to this framework, the benefit of M-TEER in patients with secondary MR depends not only on the severity of the regurgitation itself but also on the extent of the underlying left ventricular disease and remodeling.[24] Patients in whom MR is disproportionately severe relative to ventricular dilatation appear more likely to derive benefit from valve intervention than those in whom MR is largely a consequence of advanced ventricular disease.[24] Although direct comparison with these trials is not appropriate given the heterogeneous distribution of MR etiologies and the small sample size of our cohort, the symptomatic improvement and absence of heart failure hospitalizations observed during follow-up support the importance of careful multidisciplinary patient selection for M-TEER.[25]

The present study was conducted during the implementation period of the 2025 ESC/EACTS Guidelines for the management of valvular heart disease, which expanded and refined the indications for M-TEER across different MR etiologies, including its establishment as a Class I, LOE A recommendation in selected patients with persistent severe ventricular secondary MR despite optimized GDMT and CRT (if indicated), fulfilling specific clinical and echocardiographic criteria.[3] The distribution of MR etiologies treated at our institution (primary MR in 36.4%, ventricular and atrial secondary MR in 45.5%, and mixed mechanisms in 18.2%) reflects the heterogeneity of a real-world Portuguese referral population, in contrast to the more homogeneous populations evaluated in some randomized trials.[10,11,13,14] This heterogeneity was further reflected in ventricular systolic function, with mean LVEF being lower among patients with ventricular secondary MR than among those with atrial secondary MR (41.5 ± 10.6% vs 64.3 ± 3.0%), consistent with the distinct pathophysiological mechanisms underlying these entities.[26]

This study has several limitations. First, the small sample size (11 patients) and the descriptive nature of the study limit the generalization of the findings and preclude formal statistical inference. Consequently, the absence of MAEs should be interpreted with caution. Furthermore, the single-center, retrospective design and the absence of a control group prevent causal attribution of the symptomatic improvement and low heart failure hospitalization burden observed after M-TEER. Finally, the relatively short follow-up period of 6 months limits the assessment of long-term outcomes, including mortality, durability of MR reduction, and ventricular reverse remodeling. Echocardiographic assessment was not adjudicated by an independent core laboratory, and follow-up imaging was incomplete in several patients, both factors that affect the precision of the echocardiographic outcomes reported. Confirmation of these early findings will require a larger sample, complete protocolized echocardiographic follow-up, longer clinical follow-up, and ideally integration into a multicenter Portuguese or European registry.

CONCLUSION

This study demonstrates that M-TEER with the MitraClip system is feasible and safe in a center without on-site cardiac surgery, with high procedural success, sustained MR reduction, and encouraging short-term clinical outcomes. This initial experience contributes to the expanding literature on M-TEER outside traditional surgical centers and highlights the importance of structured Heart Team evaluation and careful patient selection in this setting. Beyond its academic value, it also provides real-world evidence that may support institutional decision-making regarding the consolidation and future expansion of TEER at ULSSA. Larger prospective studies with standardized echocardiographic follow-up and longer clinical surveillance are warranted to confirm the durability, reproducibility, and generalizability of these findings.

APPENDIX

TABLE I - STUDY BASELINE DEMOGRAPHIC CHARACTERISTICS (N=11).
Values are presented as n (%) or mean ± standard deviation, as appropriate. Abbreviations: CAD, coronary heart disease; PCI, percutaneous coronary intervention; CABG, coronary-artery bypass grafting; EuroSCORE II, european system for cardiac operative risk evaluation II; ARNI, angiotensin receptor-neprilysin inhibitor; ACEi/ARAII, angiotensin-converting enzyme inhibitors/angiotensin II receptor antagonists; MRA, mineralocorticoid receptor antagonists; SGLT2i, sodium-glucose cotransporter-2 inhibitors.

TABLE I. Study Baseline Demographic Characteristics (N=11)	**Data**	**n**
Age, mean ± SD, years	75.55 ± 9.35	11
Female, no. (%)	6 (54.5)	11
BMI, kg/m^2	25.97 ± 7.47	11
Arterial Hypertension, no. (%)	8 (72.7)	11
Dyslipidemia, no. (%)	7 (63.6)	11
Diabetes mellitus, no. (%)	4 (36.4)	11
History of Smoking, no. (%)	5 (45.5)	11
CAD, no. (%)	5 (45.5)	11
Previous PCI, no. (%)	2 (18.2)	11
Previous CABG, no. (%)	1 (9.1)	11
Peripheral vascular disease, no. (%)	1 (9.1)	11
Previous stroke or transient ischemic attack, no. (%)	0	11
Atrial fibrillation, no. (%)	6 (54.5)	11
Serum creatinine, mg/dL	1.29 ± 0.58	11
eGFR, mL/min	57.54 ± 23.28	11
Renal function eGFR > 60 mL/min eGFR 30-60 mL/min eGFR < 30 mL/min	 2 (18.2) 4 (36.4) 5 (45.5)	11
Chronic kidney disease requiring dialysis, no. (%)	0	11
Hemoglobin, g/dL	13,45 ± 1.83	11

TABLE I. Study Baseline Demographic Characteristics (N=11)	**Data**	**n**
Previous mitral annuloplasty ring, no. (%)	0	11
Contraindications to heart transplantation, no. (%)	4 (36.4)	11
Other significant valvular diseases (2+≥ mild to moderate severity) , no. (%) Aortic regurgitation only Tricuspid regurgitation only Aortic and tricuspid regurgitation	8 (72.7) 1 (9.1) 1 (9.1) 6 (54.5)	11
Scores		
EuroSCORE II, %	3.55 ± 1.99	11
EuroSMR score	49.35 ± 9.10	11
STS ACSD Operative Risk Calculator, %	3.58 ± 3.63	11
Related to heart failure		
NYHA functional class I II III IV	 0 4 (36.4) 6 (54.1) 1 (9.1)	11
NYHA functional class III/IV	7 (63.6)	11
Hospitalization for heart failure within previous 1 yr	8 (72.7)	11
Previous cardiac resynchronization therapy	2 (18.2)	11
Previous implantation of defibrillator	2 (18.2)	11
N-terminal pro–B-type natriuretic peptide level — pg/ml	2829.20 ± 2486.67	10
Baseline pharmacological therapy		
Beta-blockers	11 (100)	11
ARNI	1 (9.1)	11
ACEi/ARAII	4 (36.4)	11

TABLE I. Study Baseline Demographic Characteristics (N=11)	**Data**	**n**
MRA	3 (27.3)	11
SGLT2i	7 (63.6)	11
Diuretics	10 (90.9)	11
Direct oral anticoagulants	6 (54.5)	11

TABLE II - STUDY BASELINE ECHOCARDIOGRAPHIC CHARACTERISTICS (N=11).

Values are presented as n (%) or mean ± standard deviation, as appropriate. Abbreviations: SMR, secondary mitral regurgitation; MR, mitral regurgitation; RegVol, regurgitant volume; EROA, effective regurgitant orifice area; MVA, mitral valve area; VCW (2C), vena contracta width (2-chamber view); VCW (3C) , vena contracta width (3-chamber view); MVA, mitral valve area; Mitral valve complexity, Includes commissural jets, two or more significant jets, mitral valve area <4 cm^2, annular or leaflet calcification involving the grasping zone, minimal tissue for leaflet attachment (posterior leaflet length <10 mm), and flail gap >10 mm; LVEDD, left ventricular end-diastolic diameter; LVESD, left ventricular end-systolic diameter; LVEDV, left ventricular end-diastolic volume; LVESV, left ventricular end-systolic volume; LVEF, left ventricular ejection fraction; sPAP, systolic pulmonary artery pressure; TAPSE, tricuspid annular plane systolic excursion.

TABLE II. Study Baseline Echocardiographic Characteristics (N=11)	**Data**	**n**
Related to Mitral Valve		
MR severity grade 4+	11 (100)	11
MR etiology		11
Primary	4 (36.4)	
Secondary	5 (45.5)	
AtrialSMR	3 (60)	
VentricularSMR	2 (40)	
Mixed	2 (18.2)	
MR EROA, mm^2	41.80 ± 9.30	10
MR RegVol, mL	61.33 ± 17.65	10
VCW (2C), mm	7.50 ± 3.41	10
VCW (3C), mm	7.45 ± 2.30	9
MVA, cm^2	5.44 ± 1.75	11
Mitral valve complexity	8 (72.7)	11
MR jet location		11
A1/P1 (lateral)	4 (36.4)	
A2/P2 (central)	9 (81.8)	
A3/P3 (medial)	5 (45.5)	
≥ 2 jets	5 (45.5)	
Pulmonary vein flow reversal	6 (54.5)	11
Anterior leaflet length, mm	22.90 ± 2.38	10

TABLE II. Study Baseline Echocardiographic Characteristics (N=11)	**Data**	**n**
Posterior leaflet length, mm	13.55 ± 2.88	11
Bicommissural annular diameter, mm	40.33 ± 3.12	9
3-chamber annular diameter, mm	36.82 ± 3.76	11
Leaflet calcification	5 (45.5)	11
Coaptation length, mm	5.89 ± 2.67	9
Coaptation depth, mm	30.58 ± 18.75	11
Tenting área, cm^2	2.66 ± 0.61	9
Flail	4 (36.4)	11
Flail gap, mm	2.50 ± 1.91	4
Cardiac chambers and ventricular function		
LVEDD, mm	53.99 ± 11.20	11
LVESD, mm	40.74 ± 12.11	9
LVEDV, mL	130.60 ± 52.04	10
LVESV, mL	60.00 ± 34.01	9
Left atrial volume, mL	132.71 ± 49.48	11
LVEF, %	53.36 ± 11.77	11
LVEF in secondary MR, %	55.20 ± 13.66	5
LVEF in ventricular secondary MR, %	41.50 ± 10.61	2
LVEF in atrial secondary MR, %	64.33 ± 2.98	3
Right-sided echocardiographic parameters		
sPAP, mmHg	51.27 ± 20.49	11
TAPSE, mm	19.33 ± 4.47	9
TR severity ≥ 2+, moderate	6 (54.5)	11

TABLE III - PREPROCEDURAL RIGHT HEART CATHETERIZATION FINDINGS (N=11).
Values are presented as n (%) or mean ± standard deviation, as appropriate. Abbreviations: sPAP, systolic pulmonary artery pressure; dPAP, diastolic pulmonary artery pressure; mPAP, mean pulmonary artery pressure; PAWP, pulmonary artery wedge pressure; RVEDP, right ventricular end-diastolic pressure; CO, cardiac output; CI, cardiac index; PVR, pulmonary vascular resistance.

TABLE III. Preprocedural Right Heart Catheterization Findings (N=11)	**Data**	**n**
sPAP, mmHg	54.56 ± 17.82	9
dPAP, mmHg	22.63 ± 9.56	8
mPAP, mmHg	33.63 ± 12.65	8
PAWP, mmHg	19.62 ± 10.07	8
RVEDP, mmHg	9.50 ± 5.95	8
CO, L/min	3.86 ± 0.59	8
CI, L/min/m^2	2.24 ± 0.33	8
PVR, UW	3.67 ± 2.12	8

TABLE IV - PROCEDURAL OUTCOMES (N=11).
Values are presented as n (%) or mean ± standard deviation, as appropriate. Abbreviations: Device success, successful delivery and deployment of the device in the intended position, with adequate leaflet grasping and retrieval of the delivery system at the time of patient exit from the cardiac catheterization laboratory; Procedural success, proper placement of the device without procedural mortality or the need for surgical or percutaneous intervention before hospital discharge, and with effective reduction of MR, defined as a reduction to MR grade ≤2+ at discharge; Clinical success, procedural success without MAEs and with sustained clinical improvement at follow-up, including improvement in NYHA functional class and absence of heart failure hospitalization at 6 months.

TABLE IV. Procedural Outcomes (N=11)	**Data**	**n**
Number of devices implanted		11
1	5 (45.5)	
2	5 (45.5)	
3	1 (9.1)	
Number of devices implanted devices	1.64 ± 0.67	11
Procedure limited by transmitral gradient, no. (%)	1 (9.1)	11
Device success, no. (%)	11 (100)	11
Procedural success, no. (%)	10 (90.9)	11
Clinical success, no. (%)	10 (90.9)	11
Length of hospital stay, days	3.18 ± 3.92	11
Patients discharged home	11 (100)	11
Postprocedural MR severity		11
Grade 0+	0	
Grade 1+	2 (18.2)	
Grade 2+	8 (72.7)	
Grade 3+	1 (9.1)	
Grade 4+	0	
Mitral gradient pre-procedure, mmHg	2.10 ± 0.77	10
Mitral gradient post-procedure, mmHg	2.73 ± 1.10	11
MVA pre-procedure, cm^2	5.44 ± 1.75	11
MVA, post-procedure, cm^2	2.75 ± 0.76	9

TABLE V - CLINICAL AND ECHOCARDIOGRAPHIC FOLLOW-UP (N=11).
Values are presented as n (%) or mean ± standard deviation, as appropriate. Abbreviations: HF, heart failure; ΔLVEDD, change in left ventricular end-diastolic diameter between baseline and 6-month follow-up; ΔLVESD, change in left ventricular end-systolic diameter between baseline and 6-month follow-up; ΔLVEDV, change in left ventricular end-diastolic volume between baseline and 6-month follow-up; ΔLVESV, change in left ventricular end-systolic volume between baseline and 6-month follow-up; ΔLA volume, change in left atrial volume between baseline and 6-month follow-up; ΔLVEF, change in left ventricular ejection fraction between baseline and 6-month follow-up; ΔsPAP, change in systolic pulmonary artery pressure between baseline and 6-month follow-up; ΔTAPSE, change in tricuspid annular plane systolic excursion between baseline and 6-month follow-up; ΔMR EROA, change in Mitral Regurgitation Effective Regurgitant Orifice Area between baseline and 6-month follow-up.

TABLE V. Clinical and Echocardiographic Follow-Up (N=11)	**Data**	**n**
Clinical Outcomes		
HF hospitalization within 6 months of follow-up	0	11
Improvement in NYHA functional class	8 (72.7)	11
NYHA functional class III/IV	1 (9.1)	11
Mitral Regurgitation Outcomes		
≥ 1 grade reduction in MR	11 (100)	11
Echocardiographic Follow-Up		
ΔLVEF, %	3.50 ± 9.15	4
ΔLVEDD, mm	0.37 ± 5.73	3
ΔLVESD, mm	5.00 ± 1.41	2
ΔLVEDV, mL	40 ± 31.51	3
ΔLVESV, mL	31 ± 0	1
ΔLA volume, mL	-7.50 ± 42.4	4
ΔsPAP, mmHg	-19 ± 0	1
ΔTAPSE, mm	3.33 ± 6.03	3

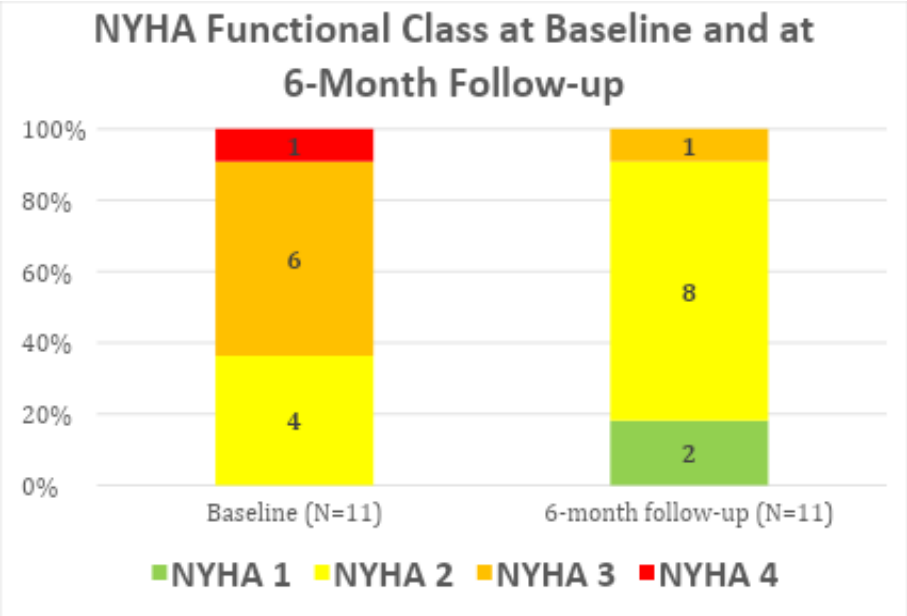

FIGURE 1 - Distribution of NYHA functional class at baseline and 6-month follow-up

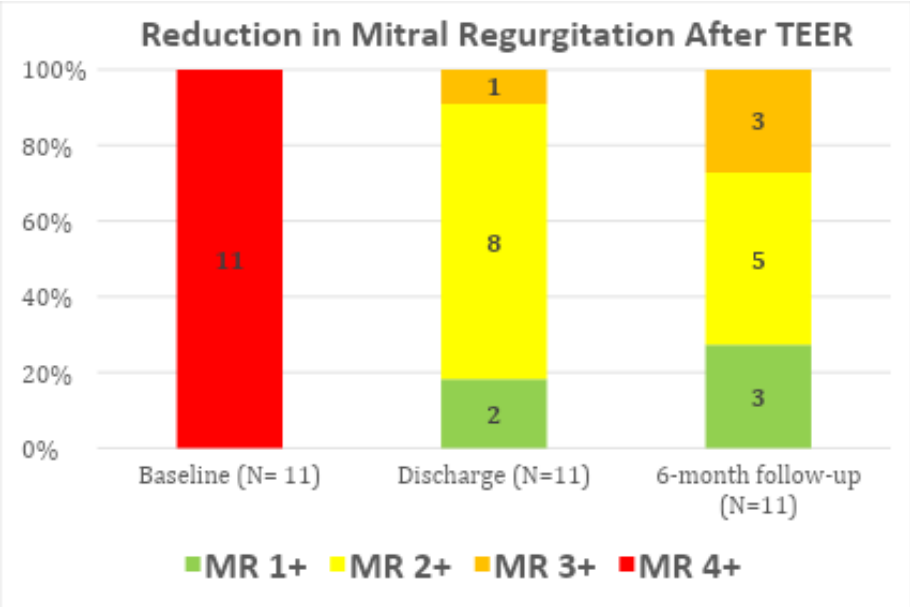

FIGURE 2 - Distribution of mitral regurgitation severity at baseline, discharge, and 6-month follow-up after TEER

REFERENCES

1. Nkomo VT, Gardin JM, Skelton TN, et al. Burden of valvular heart diseases: a population-based study. Lancet. 2006;368(9540):1005-11.
2. Enriquez-Sarano M, Akins CW, Vahanian A. Mitral regurgitation. Lancet. 2009;373(9672):1382-94.
3. Praz F, Borger MA, Lanz J, et al. 2025 ESC/EACTS Guidelines for the management of valvular heart disease. Eur Heart J. 2025;46(44):4635-736.
4. Dal-Bianco JP, Beaudoin J, Handschumacher MD, et al. Basic mechanisms of mitral regurgitation. Can J Cardiol. 2014;30(9):971-81.
5. Hausleiter J, Stocker TJ, Adamo M, et al. Mitral valve transcatheter edge-to-edge repair. EuroIntervention. 2023;18:957-76.
6. Nappi F. Comparing surgical techniques and results of secondary ischemic mitral regurgitation: a state-of-the-art literature review. Ann Transl Med. 2024;12(5):91.
7. Suradi HS, Kavinsky CJ, Hijazi ZM. Percutaneous mitral valve repair: The MitraClip device. Glob Cardiol Sci Pract. 2016;2016(2):17.
8. von Bardeleben RS, Mahoney P, Morse MA, et al. 1-year outcomes with fourth-generation mitral valve transcatheter edge-to-edge repair from the EXPAND G4 study. JACC Cardiovasc Interv. 2023;16(21):2600-10.
9. Feldman T, Foster E, Glower DD, et al. Percutaneous repair or surgery for mitral regurgitation. N Engl J Med. 2011;364(15):1395-406.
10. Stone GW, Lindenfeld J, Abraham WT, et al. Transcatheter mitral-valve repair in patients with heart failure. N Engl J Med. 2018;379(24):2307-18.
11. Obadia JF, Messika-Zeitoun D, Leurent G, et al. Percutaneous repair or medical treatment for secondary mitral regurgitation. N Engl J Med. 2018;379(24):2297-2306.
12. Stone GW, Abraham WT, Lindenfeld J, et al. Five-Year Follow-up after Transcatheter Repair of Secondary Mitral Regurgitation. N Engl J Med. 2023;388:2037-2048.
13. Anker SD, Friede T, von Bardeleben RS, et al. Transcatheter Valve Repair in Heart Failure with Moderate to Severe Mitral Regurgitation. N Engl J Med. 2024;391(19):1799-809.
14. Baldus S, Doenst T, Pfister R, et al. Transcatheter repair versus mitral-valve surgery for secondary mitral regurgitation. N Engl J Med. 2024;391(19):1787-1798.

15. Neema PK, Panidapu N. The mechanisms and pathophysiology of mitral regurgitation: A narrative review. Ann Card Anaesth. 2025;28:109-18.
16. Pibarot P, Delgado V, Bax JJ. MITRA-FR vs. COAPT: lessons from two trials with diametrically opposed results. Eur Heart J Cardiovasc Imaging. 2019;20(6):620-4.
17. Stocker TJ, Stolz L, Karam N, et al. Long-Term Outcomes After Edge-to-Edge Repair of Secondary Mitral Regurgitation: 5-Year Results From the EuroSMR Registry. JACC Cardiovasc Interv. 2024;17(21):2543-54.
18. Lurz P, Schmitz T, Geisler T, et al. Mitral Valve Transcatheter Edge-to-Edge Repair: 1-Year Outcomes From the MiCLASP Study. JACC Cardiovasc Interv. 2024;17(7):890-903.
19. Mehran R, Rao SV, Bhatt DL, et al. Standardized Bleeding Definitions for Cardiovascular Clinical Trials: A Consensus Report From the Bleeding Academic Research Consortium. Circulation. 2011;123(23):2736-47.
20. Stone GW, Adams DH, Abraham WT, et al. Clinical Trial Design Principles and Endpoint Definitions for Transcatheter Mitral Valve Repair and Replacement: Part 2: Endpoint Definitions. J Am Coll Cardiol. 2015;66(3):308-21.
21. Malaisrie SC, Guerrero M, Davidson C, et al. One-year outcomes of transseptal mitral valve-in-valve in intermediate surgical risk patients. Circ Cardiovasc Interv. 2024;17:e013782.
22. Babić D, Benko Meštrović S, Bertić Ž, et al. The role of EuroSCORE II in predicting postoperative pressure injuries in cardiac surgery patients: a cross-sectional study. Healthcare. 2025;13:2880.
23. Hausleiter J, Lachmann M, Stolz L, et al. Artificial intelligence-derived risk score for mortality in secondary mitral regurgitation treated by transcatheter edge-to-edge repair: the EuroSMR risk score. Eur Heart J. 2024;45:922–936.
24. Grayburn PA, Sannino A, Packer M. Proportionate and disproportionate functional mitral regurgitation: a new conceptual framework that reconciles the results of the MITRA-FR and COAPT trials. JACC Cardiovasc Imaging. 2019;12(2):353-362.
25. Koell B, Orban M, Weimann J, et al. Outcomes stratified by adapted inclusion criteria after mitral edge-to-edge repair. J Am Coll Cardiol. 2021;78(24):2408-2421.
26. Venturiello D, Campolongo G, Navarra EM, Speziale G. Atrial secondary mitral regurgitation: pathophysiology, diagnosis, and surgical implications. Medicina. 2026;62:520.

INSTITUTO DE **CIÊNCIAS BIOMÉDICAS ABEL SALAZAR**