Percutaneous Mitral Valve Repair
Review of Current Techniques and Evidence

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Abstract

Over the past years, the area of transcatheter heart valve repair has seen steady evolution. Percutaneous repair for mitral regurgitation, specifically, has recently gained substantial interest, many years after the first percutaneous balloon mitral valvuloplasty was introduced as an alternative to surgery in patients with mitral stenosis. While a multitude of transcatheter mitral repair devices have been developed, most of these devices are still in the preclinical phase. The wide variety of mitral repair devices target the different mechanisms of mitral regurgitation that depend mainly on the etiology of mitral regurgitation. Clinical data support the use of transcatheter edge-to-edge repair devices, with few data supporting the use of other devices. Patient and device selection are essential to procedural and clinical success. The purpose of this review is to highlight the different devices that have been developed for percutaneous mitral valve repair together with the clinical data that backs up their application.

Introduction

Mitral valve (MV) pathology constitutes 15% of cases of death due to valvular heart disease. The most common primary mitral valve pathology worldwide is mitral prolapse, which affects 2 to 3% of the total population, whereas the most frequent primary mitral valve disorder that leads to hospitalization is rheumatic heart disease.(1)

Secondary mitral regurgitation (MR) accounts for the majority of cases of moderate to severe MR. About 24% of patients with systolic congestive heart failure have significant MR. Secondary MR is more common in developed countries in which atherosclerosis, ischemic heart disease, and heart failure are more prevalent. All these factors are associated with secondary MR.(1)

Patients with significant mitral valve regurgitation have long been treated with surgical valve repair or replacement. Nevertheless, up to 49% of patients who require MR repair or replacement are denied surgery because they are deemed to be at high risk for surgical intervention.(2) Consequently, the need for transcatheter mitral valve interventions escalated, in an effort to improve the outcomes in patients with high surgical risk, and potentially other patients as well.

Pathology of mitral regurgitation(3, 4)

Mitral regurgitation can be categorized as acute or chronic and primary or secondary. The mechanisms of mitral regurgitation are best illustrated by Carpentier's classification, which classifies MR into three categories:

Type I (normal leaflet mobility): including endocarditis (perforation of a leaflet), degenerative (calcification of the annulus), congenital (leaflet cleft), atrial MR, and dilated cardiomyopathy.

Type II (excessive leaflet mobility): including degenerative (leaflet prolapse, ruptured chordae), endocarditis (ruptured chordae), ischemic (ruptured papillary muscle) and traumatic (ruptured chordae).

Type IIIa (restricted leaflet mobility in both systole and diastole): including post-inflammatory (rheumatic heart disease, Libmann-Sacks endocarditis, endomyocardial fibrosis, eosinophilic endocardial disease) and drug-induced.

Type IIIb (restricted leaflet mobility in systole only): including papillary muscle ischemia and ischemic cardiomyopathy.

Secondary MR implies that the mitral leaflets and chordae are intact, corresponding to type IIIb and some of type I Carpentier classification.
Understanding the mechanism(s) of MR in each patient is of paramount importance when mitral valve interventions are planned since the mechanism(s) will greatly influence patient selection and dictate the type of intervention needed.

Devices for transcatheter mitral valve repair:

A. Coaptation Devices:

I. Direct coaptation devices

Mitraclip:

The most researched device by far for treating functional and primary (degenerative) mitral regurgitation. A steerable guiding catheter and a clip delivery system make up the system. The MitraClip G4 system, which is the fourth generation, has four improvements: four clip sizes (NT, XT, NTW, XTW), a controlled gripper actuator (CGA) function that enables grasping of a single leaflet or both leaflets simultaneously, integrated left atrial pressure monitoring and simplified system preparation and deployment.[5]

The clip is composed of two nitinol-based grippers and two arms made of cobalt-chromium alloy. Four (NT/NTW) or six (XT/XTW) longitudinally arranged hooks are present on the grippers. Larger coaptation gaps and flail leaflets can be treated with longer clip arms (XT/XTW). When the clip arms close, the grippers hold the leaflets steady while they are being captured. On each side, leaflet tissue is secured between the gripper and the arm. Pressure gradients are evaluated in order to make sure that there is no significant clip-induced mitral stenosis, If necessary, a second or third clip can be placed. (figure 1).[5, 6]

The CGA allows the use of additional maneuvers besides simultaneous leaflet capture such as leaflet optimization or staged leaflet capture. For leaflet optimization, the arms are reopened after simultaneous capture of both leaflets, followed by selective opening of the grippers to ensure adequate insertion of each leaflet. Slight rotation of the device to improve coaxiality is also allowed at this point. Staged leaflet capture is a less commonly used technique in which one leaflet is captured and secured by the device, followed subsequently by capturing the other leaflet.[6]

PASCAL:

Three parts make up the PASCAL system (Edwards Lifesciences, Irvine, California, USA): an implanted catheter, a steerable sheath, and a guide sheath. The PASCAL (10 mm width) and PASCAL Ace (6 mm width) are the two implant sizes available. Three distinct planes of movement are possible thanks to the independent movement of the three catheters. The implant consists of two paddles, two clasps, and a central spacer. Leaflet approximation is possible with the two paddles. With their single row of hooks, the two clasps enable the separate capture and adjustment of each leaflet. By filling the space between the leaflets, the central spacer fills the gap between the leaflets and aids in minimizing MR. The PASCAL system has the ability to elongate, allowing it to be safely retracted from the subvalvular apparatus without damage to the chordae. The leaflet optimization and staged leaflet capture techniques can be performed with this system as well (figure 2). [5, 6]

Preclinical testing for additional edge-to-edge repair devices is presently underway. These devices include the Cardiac Mitral Repair system (AesDex, LLC, Palo Alto, CA, USA) and the Mitraflex system (TransCardiac Therapeutics, Atlanta, GA, USA).[7]

Although patients receiving treatment have a high burden of comorbidities, mitral valve TEER is thought to be a safe procedure with a manageable rate of complications. Potential side effects include: hemodynamically relevant interatrial septal defect (incidence unknown), significant bleeding, perforation, rupture, dissection: 1.4–4.0%; pericardial effusion or tamponade (0-0.5%); single leaflet device attachment (1.5–5.1%); device embolization (0.05–0.70%); leaflet injury (0–2%); residual significant MR (3.4–17.0%); high trans mitral gradient >5 mmHg (Up to 15%); major vascular complications (severe bleeding, perforation, rupture, dissection: 1.4–4.0%); myocardial infarction (0–3%); cerebrovascular stroke (0–1%).[6]

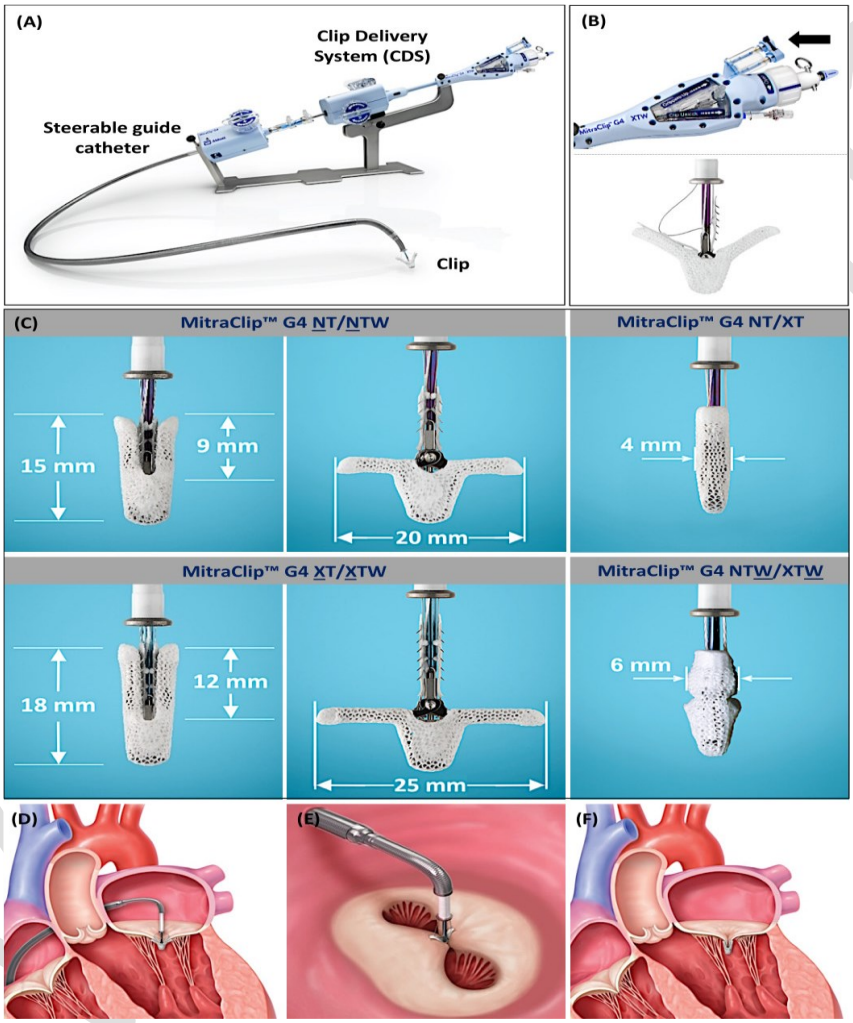

Figure (1)

Figure 1: (A) Components of the MitraClip G4 system. (B) Two separate gripper levers to allow independent leaflet grasping. (C) Four available clips (NT, XT, NTW, and XTW). (D) The clip is passed across the leaflets into the left ventricle, then gently pulled back till the leaflets are grasped by the grippers. (E) Once the clip is closed, a double orifice mitral valve opening can be seen from the 3D-TEE surgeon's view. (F) Final result. Images courtesy of Abbott.[5]

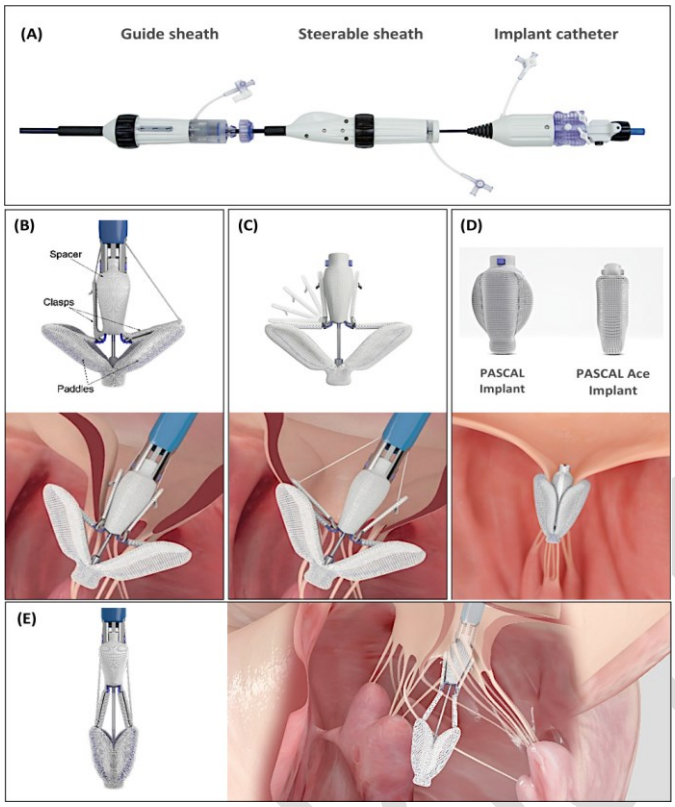

Figure (2)

Figure 2: (A) The three components of the PASCAL delivery system. (B) The PASCAL implants. (C) Independent leaflet capture. (D) The paddles on the most recent generation PASCAL Ace implant are 6 mm wide, and the spacer is smaller. (E) The PASCAL device's elongation makes it easier to retract from the left ventricle when necessary and lowers the risk of being tangled in the chords. Images courtesy of Edwards Lifesciences.[5]

Table 1: Main differences between the MitraClip and the PASCAL mitral repair systems[6]

	Mirtaclip (4th generation)	**Pascal Precision (2nd generation)**
Delivery catheter	2 components	3 components
Available clip sizes	4	2
Device material	Cobalt-chromium (rigid)	Nitinol (flexible)
Closure mechanism	Active	Passive
Central spacer	No	yes
Arrangement of hooks	Longitudinal	Horizontal
Continuous left atrial pressure monitoring	yes	yes

II. Indirect coaptation devices

The Mitra spacer is an indirect coaptation device that aims at improving leaflet coaptation by filling a space in the mitral valve orifice. It consists of a trans-apically delivered balloon that is filled with fluid and is attached to the LV apex by an anchor HeartPad (B. Braun, Melsungen, Germany). The balloon is attached to a subcutaneous reservoir that enables adjustment of the spacer's fluid content. Technically, the first-in-human implantation went well, and the severity of MR was decreased to moderate. Nevertheless, despite anticoagulation, device thrombosis appeared after eight months, which necessitated valve replacement.[7]

Another indirect coaptation device is the Mitralix. It is a spiral-shaped device that is positioned inside the left ventricle to pull the chordae together. This device has not passed the preclinical stage yet.[8]

B. Annuloplasty Devices

1- Direct annuloplasty devices

A transseptal access is used to administer the transcatheter mitral annuloplasty device known as the Cardio band Mitral System (Edwards Lifesciences, Irvine, CA, USA). A device that aims to decrease the mitral annular' circumference in order to enhance leaflet coaptation. The implant consists of a polyester sleeve with radiopaque markers. The delivery mechanism that releases screw anchors is covered by the sleeve. Multiplanar 3D transesophageal echocardiography (TEE) is used to guide the lateral and anterior placement of the first anchor in the mitral annulus. A coronary angiography is then performed to rule out left circumflex coronary artery damage. Subsequently, the anchors are positioned until they reach the medial end of the posterior mitral annulus. The device can then contract by cinching a contraction wire. (figure 3).[5]

Another transseptal direct annuloplasty device in development is the Millipede (IRIS) system (Boston Scientific in Massachusetts, USA). It consists of a complete semi-rigid ring that is joined to the mitral annulus by eight slider components that are connected to eight anchors. Each slider component can be individually tightened to allow for precise mitral annular size adjustment. Additionally, the apparatus has an integrated intracardiac echocardiography catheter that goes through the delivery catheter's central lumen.[5]

The Mitralign system (Mitralign, Tewksbury, MA, USA) is an annuloplasty device that is delivered via a transfemoral, transventricular approach. Two pledgets are placed on opposing sides of the mitral annulus. In order to reduce annular dilatation, the pledgets are plicated on the ventricular side of the mitral annulus. This device is presently in the preclinical stage..[8]

Preclinical testing is currently underway for additional transcatheter direct annuloplasty devices, such as the Amend system (Valcare Medical, Herzliya Pituah, Israel), the Mitrals Restriction Ring (Cardiac Implant Solutions, Jacksonville, FL, USA), the Kardium MR device (Kardium, Burnaby, BC, Canada) and QuantumCor (QuantumCor, Lake Forest, CA, USA).[8]

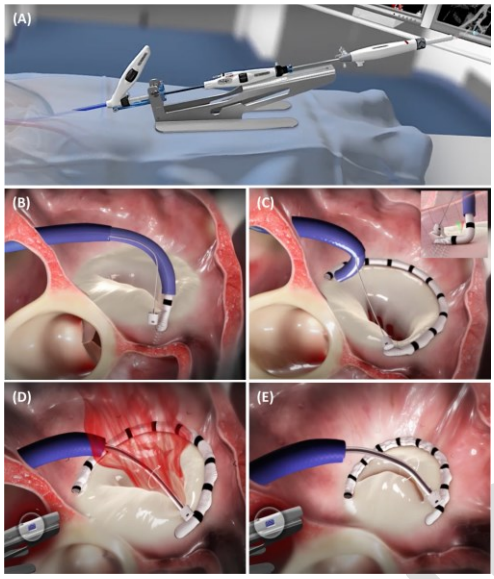

Figure (3)

Figure 3: (A) The Cardioband delivery system. (B) Placing the first anchor at the mitral annulus's lateral and anterior surface. (C) subsequent lateral to the medial placement of anchors. (D and E) The mitral annulus contracts as a result of the Cardioband device being cinched. Images courtesy of Edwards Lifesciences.[5]

2- Indirect annuloplasty devices

Indirect mitral annuloplasty devices utilize the left atrium or the coronary sinus to reduce the mitral annular size.

The Carillon mitral contour system (Cardiac Dimensions, Kirkland, WA, USA) consists of two anchors joined by a ribbon connector. A specialized sizing catheter is used to measure the size of the great cardiac vein and the coronary sinus. Subsequently, the implant is inserted into the coronary sinus using a transjugular approach. The coronary sinus contains the proximal anchor, while the great cardiac vein houses the distal anchor. Afterwards, the central ribbon is shortened to allow a reduction in the posterior annular size. The degree of reduction in MR can be adjusted during the procedure, as the device can be repositioned or retrieved using the same delivery system. Limitations of this device are its ineffectiveness if the coronary sinus is distant from the mitral valve, the risk of damage to the left circumflex artery, and the inability to use it if the patient has an implanted cardiac resynchronization therapy (CRT) (figure 4).[5]

Currently in development is another indirect annuloplasty device called the ARTO system (MVRX, San Mateo, CA, USA). It consists of a suture that passes through two anchors: one is placed in the interatrial septum and is connected to the lateral atrial wall via the great cardiac vein. The anteroposterior annular diameter decreases once the suture is contracted.[5]

C. **Chordal implantation**

These devices are mainly indicated for primary MR due to mitral prolapse or flail leaflet, ideally before annular dilatation ensues.

The NeoCord (NeoCord, St. Louis Park, MN, USA) is a CE-approved chordal repair system. It is delivered transapically via a left lateral mini-thoracotomy under general anesthesia and TEE guidance. The jaws of the device are used to grasp the mitral valve leaflet. A girth hitch suture is then passed through the mitral leaflet and is attached to an apical epicardial pledget. Multiple chords can be used (figure 5).[5]

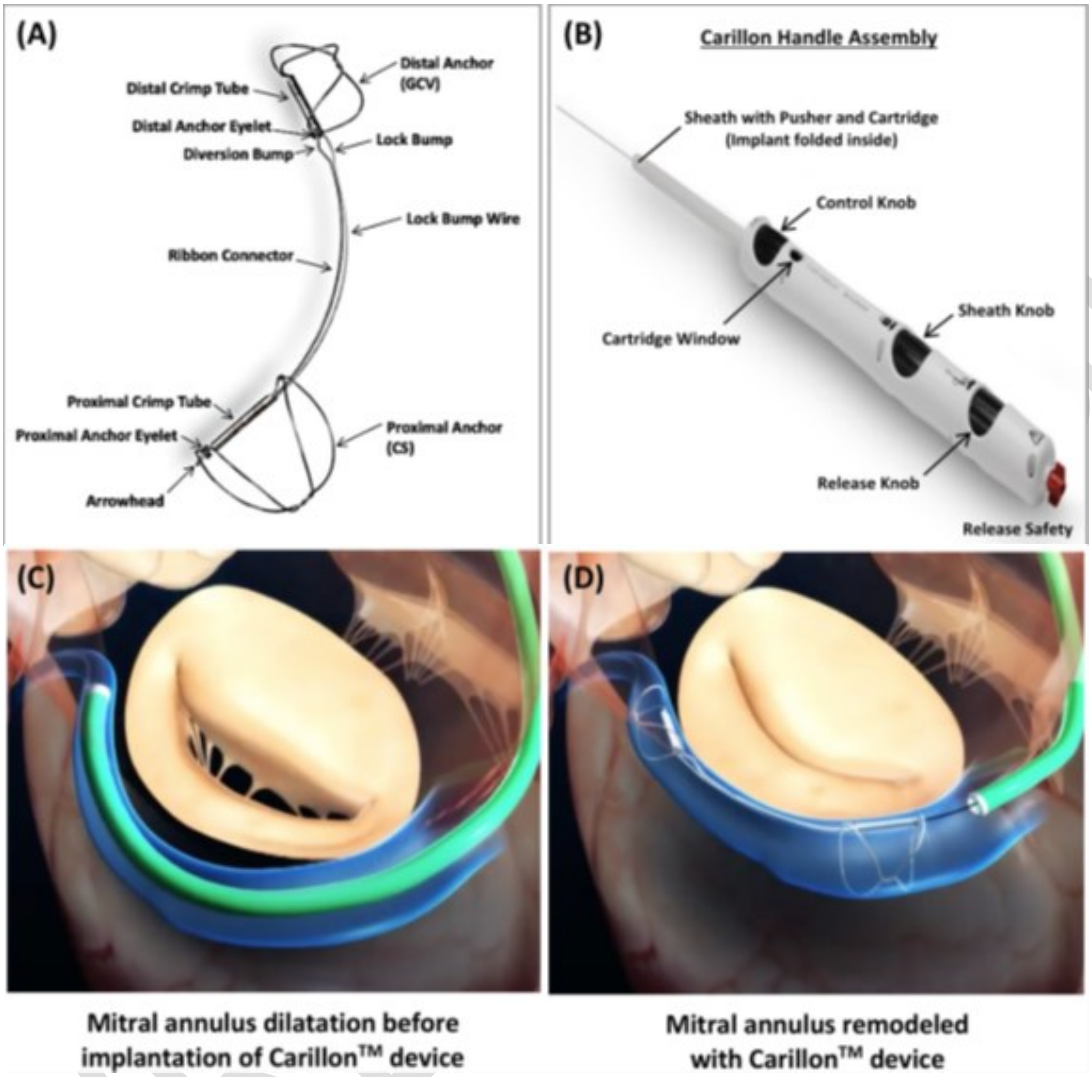

Figure (4)

Figure 4: (A) Components of the Carillon implant. (B) Components of the Carillon Handle. (C and D) Device deployment in the coronary venous system. Images courtesy of Cardiac Dimensions.[5]

The Harpoon MVRS (Edwards Lifesciences, Irvine, CA, USA) is another transapically delivered device that utilizes a harpoon to attach a helical suture to the tip of the posterior leaflet. Multiple chords are usually used then passed through a Teflon pledget. The chords can be individually tensioned to achieve the desired coaptation.[5]

Additional chordal implantation devices in development are the V-Chordal TF (Valtech Cardio, Or Yehuda, Israel), the MISTRAL (Mitralix, Jerusalem, Israel), and the ChordArt (Coremedic GmbH, Tuebingen, Germany).[8]

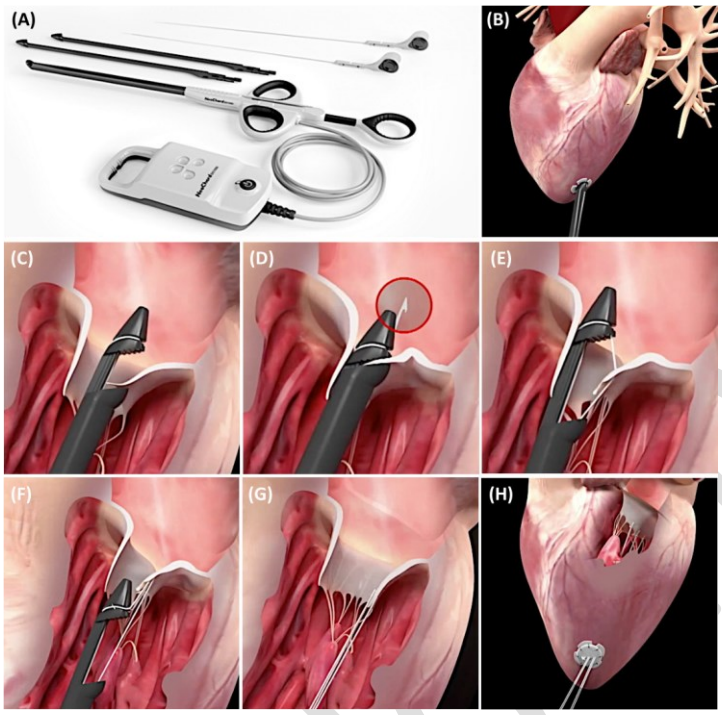

Figure (5)

Figure 5: (A) Components of the NeoCord system. (B) The optimum access is 2- 3 cm from the true LV apex. (C and D) The device jaws seize the mitral leaflet. (E and F) A girth hitch suture is inserted through the leaflet. (G and H) The cord is attached to an apical pledget. Images courtesy of NeoCord.[5]

D. Ventricular remodeling devices[7]

These devices aim to reduce secondary MR by reducing LV dilatation. None of them has gained FDA or CE approval yet.

A device that uses a transfemoral approach to deliver a series of nitinol anchors is the AccuCinch system (Ancora Heart, Santa Clara, CA, USA). Ventriculoplasty and MR reduction are achieved once the anchors are implanted in the subvalvular space and then cinched.

In the Ven Touch system (Mardil Medical, Minneapolis, MN, USA), a left-sided mini-thoracotomy is used to insert a bladder that surrounds both ventricles. The inflation of specific LV pads improves leaflet coaptation and reduces MR by decreasing the size of the mitral annulus and the left ventricle.

Clinical evidence

1) TEER:

The MitraClip has the most robust clinical evidence among transcatheter mitral valve repair systems. Data on primary MR are mainly derived from studies that were performed on first and second-generation MitraClip. EVERESTII was a randomized clinical trial (RCT) that involved 297 patients, the majority of whom had grade 3+ or 4+ MR (73% primary MR). The cohort were randomized to MV repair by MitraClip versus surgical repair. MitraClip had a superior safety profile with a major adverse events rate of 15% compared to

48% in the surgery group. However, surgical repair turned out to be more effective; following surgical repair, the rate of surgery for mitral valve dysfunction was 2% as opposed to 20% in the group that underwent percutaneous intervention.[9]

The use of third generation MitraClip (NTR or XTR) in 1041 patients with high surgical risk was assessed by the EXPAND registry. 40.5% of patients had primary MR or mixed etiology. The population had a mean age of 79.5 ± 9.4 years. Results showed a low 30-day adverse event rate (2.4% for all-cause mortality and 1.2% for stroke). In terms of efficiency, at 30 days MR was reduced to grade ≤1+ in 86.9% and to grade ≤2+ in 97.3% of cases. It is worth noting 29% of patients had mitral leaflet pathologies (62.6% with severe leaflet degeneration or large flail gaps, 35.7% with calcification in the landing zone, and 29.6% with very wide MR jets). At 30-day follow up, MR reduction to grade ≤1+ still reached 79.4%, and MR ≤2+ reached 96.9% in this group.[6]

Regarding secondary MR, guidelines-directed medical therapy (GDMT) and MitraClip were compared for efficacy in two significant RCTs: the COAPT and MITRA-FR trials. In the COAPT trial, 614 patients with moderate to severe or severe MR and heart failure were randomized to receive MitraClip plus GDMT instead of GDMT alone. In comparison to the group treated with GDMT alone, the MitraClip group experienced a 24-month reduction in all-cause mortality (HR = 0.62) and a decreased rate of hospitalization for heart failure (hazard ratio [HR] = 0.53). 96.6% of subjects met the primary safety endpoint of the absence of device-related complications after one year).[10] In the MITRA-FR study, 304 patients with severe secondary MR, heart failure, and an EF of 15–40% were randomized to receive MitraClip in addition to medical therapy or medical therapy only. At 12 months, there were no significant differences between the two groups with respect to hospitalization for heart failure (48.7% in the intervention group versus 47.4% in the control group) or all-cause mortality (24.3% in the intervention group versus 22.4% in the control group), which seemed to contradict the COAPT results.[11]

These controversial findings emphasized the significance of patient selection and the effect of left ventricular dysfunction on procedural outcomes. The following differences between the two studies may help to explain the variations in the results:

Endpoints: no safety endpoint was present in the MITRA-FR study, and the primary efficacy endpoint was assessed at 12 months as opposed to 24 months in the COAPT trial. Nonetheless, the benefit remained noteworthy in a post-hoc analysis of the COAPT trial's primary efficacy endpoint at 12 months. Furthermore, a 24-month follow-up of the MITRA-FR patients did not reveal any significant clinical benefit.[12, 13]

Echocardiographic criteria: compared to the MITRA-FR, patients with less severe LV dilatation and dysfunction and more severe MR were included in the COAPT trial. Patients with 3+ or 4+ MR were included in the COAPT trial. The majority of these patients (about 85%) had an EROA of ≥0.3 cm2, and in cases where the EROA was less than 0.3 cm2, additional requirements had to be met in order to be included. In the MITRA-FR, an EROA of ≥0.2 cm2 or a regurgitant volume of >30 ml/beat were used to identify severe MR. Only 48% of the subjects had an EROA of ≥0.3 cm2. Furthermore, patients with an LVEF of 20% to 50% and a left ventricular end-systolic dimension of less than 70 mm were excluded from COAPT. The mean LVEDV was 101±34 mL/m2. On the other hand, patients with an LVEF of 15%–40% were included in the MITRA-FR, without restrictions to the LV dimensions. The mean LVEDV was 135±35 mL/m2.[12]

Optimization of GDMT: the COAPT trial strictly required optimization of medical management, as well as CRT implantation or coronary revascularization, if indicated, before randomization. Any change in medical management during follow-up was reported to a specific committee. On the contrary, the adequacy of GDMT in the MITRA-FR trial was assessed by the

trialists, and any change in medical management during follow-up was left to the discretion of the treating physician, without documentation.

Operator experience: There is no direct evidence regarding the operator's experience in both studies. In contrast to MITRA-FR, the COPAT study had fewer patients with post-procedural residual 3–4+ MR (5% vs. 9%). At 1-year follow up, the prevalence of 3-4+ MR was also lower among the COAPT patients (17% vs. 5%). In the COAPT study, the complication rate (which included tamponade, cardiogenic shock, and device implant failure) was 8.5% as opposed to 14.6% in the MITRA-FR.

After five years of follow-up, the COAPT patients' outcomes were reevaluated, and the clinical benefit was still statistically significant. The device group outperformed the medical therapy group in terms of all-cause mortality or heart failure hospitalization at 5 years (73.6% versus 91.5%, HR = 0.53). Additionally, the device group experienced a lower annualized rate of hospitalization for heart failure (33.1% versus 57.2% annually, HR = 0.53). In the device group, the 5-year all-cause mortality was 57.3%, while in the control group, it was 67.2% (HR = 0.72).[14]

It is clear that the COAPT trial had a very selective approach regarding patient enrollment and follow-up, while the MITRA-FR study had a less strict, real-world design. To further explain the difference between the results of the 2 trials, the concept of proportionate vs disproportionate MR was introduced. The EROA is expected to increase as the end-diastolic volume increases in patients with a reduced EF. In case of severe LV dilatation, a large EROA may not indicate severe MR or in other words, may not indicate a degree of MR that will benefit from valvular intervention.[15]

In order to implicate the findings from both trials into clinical practice, the COAPT criteria were set as a benchmark for patients' eligibility to a MitraClip procedure (Table 2). However, In the large retrospective EuroSMR registry, patients who underwent mitral TEER -both COAPT-eligible and COAPT-ineligible- showed improvement in their quality of life and their exercise capacity.[16] The New York heart association (NYHA) class also showed significant improvement.[17] Moreover, clinical improvement was observed regardless of the EROA.[18]

Table 2: Simplified COAPT criteria for mitral TEER[6]

COAPT criteria for mitral valve TEER	
Favouring TEER	**Against TEER**
• Severe secondary MR • NYHA class II, III, or ambulatory IV • On maximum tolerated GDMT • LVEF 20-50% • LV end-sytolic diameter <70 mm • At least on hospitalization for heart failure within the previous year or increased natriuretic peptide levels (BNP ≥300 pg/ml or NT-proBNP ≥1,500 pg/ml) • Anatomy suitable for TEER	• Hemodynamic instability (SBP ≤90 mmHg, cardiogenic shock, or the need for inotropic and/or mechanical supports) • Advanced heart failure • Moderate or severe RV dysfunction • Pulmonary artery systolic pressure >70 mmHg • COPD requiring oxygen therapy or steroids • Coronary or other valvular disease requiring surgery • Hypertrophic, restrictive, or infiltrative cardiomyopathy

Abbreviations: COPD: chronic obstructive pulmonary disease, GDMT: guidelines-directed medical therapy, LV: left ventricle, LVEF: left ventricular ejection fraction, NYHA: New York Heart Association, SBP: systolic blood pressure, TEER: transcatheter edge-to-edge repair,

The CLASP study demonstrated the safety and effectiveness of the PASCAL System in the treatment of patients with both functional and degenerative MR. Procedural and clinical success were achieved in 92% and 87% of cases, respectively. MR was reduced to ≤2+ in 98% of patients at 30 days and 100% of patients after a year. At 1 year, the overall population's survival rate was 92%, while the survival rates for the functional and degenerative MR populations were 89% and 96%, respectively. Additionally, there was a notable improvement in both functional ability and quality of life.[19, 20]

A recently published metanalysis on the PASCAL system included 12 observational studies and one RCT (1028 patients in total) with a high surgical risk. 51.8% of patients had secondary MR and 99.7% had ≥3+ MR. Technical success rates ranged from 90 to 100% and procedural success at 30 days ranged from 87 to 98%. MR was reduced to ≤2+ in 93.6% of patients at discharge and 90.4% at 30-day follow-up. Following

MitraClip is being compared to surgical mitral valve repair in high- and low-risk patients in the currently enrolling RCTs REPAIR-MR (ClinicalTrials.gov: NCT04198870), PRIMARY (ClinicalTrials.gov: NCT05051033), and MITRA-HR (ClinicalTrials.gov: NCT03271762). The CLASP IID/IIF (ClinicalTrials.gov: NCT03706833) study compares MitraClip MV repair to PASCAL in patients with primary (IID) or secondary (IIF) severe MR who have prohibitive surgical risk.

2) Annuloplasty devices:

120 patients with moderate to severe secondary MR and heart failure were included in the randomized controlled study REDUCE FMR. Patients were randomized to a sham procedure or the Carillon device. The device group demonstrated a mean reduction in regurgitant volume of 10.4 mL per beat (p = 0.049) at the 12-month follow-up, along with a reduction in left ventricular volume, although there was no discernible change in ejection fraction.[23]

The Cardio band system's feasibility was examined in 31 patients who had secondary MR. The implantation, mortality was 4.54% and 12.2 at 30 days and 1 year, respectively. The PASCAL system seemed safe and efficient in high-surgical risk patients with severe MR.[21]

Multiple predictors of adverse outcomes after mitral valve TEER have been identified:[22]

a. Clinical factors: previous valve intervention, atrial fibrillation, renal impairment, ischemic cardiomyopathy, high STS and Euro score, high NYHA functional class.
b. Baseline echocardiography: larger flail width, reduced LV function, dilated LV dimensions, high pulmonary artery pressure, reduced RV function, restricted leaflet motion, significant tricuspid regurgitation.
c. Procedural factors: intraprocedural complications, residual MR, mitral stenosis, and high left atrial pressure.
d. Biomarkers: high NT-pro BNP and Troponin T.

anteroposterior annular diameter was successfully decreased by the device by more than 30%. At the 6-month follow-up, 86.3% of patients had MR reduced to ≤ 2+. The mortality rate in hospital and at one month was 5%, whereas the rate at seven months was 9.7%.[24] 60 patients participated in another prospective multicenter trial, which revealed 97%, 72%, and 68% technical, device, and procedural success rates, respectively. Overall survival at a 1-year follow-up was 87%, and survival without reintervention was 78%. There were two coronary artery complications, one stroke, one pericardial tamponade, and ten anchor dislodgements resulting in reintervention in five patients.[25]

The multicenter, prospective, non-randomized MAVERIC trial evaluated the ARTO system. 45 patients with secondary MR grade ≥2+ despite GDMT and NYHA Class II-IV systolic heart failure underwent ARTO device implantation. At 30 days and 1 year, 4.4% and 17.8% of patients, respectively, met the primary safety composite endpoint of death, stroke, myocardial infarction, device-related surgery, cardiac