ORIGINAL ARTICLE

Single-center experience with percutaneous mitral valve repair using the MitraClip in a high-risk series in Turkey

Türkiye'de yüksek cerrahi riskli mitral yetersizlikli olgularda MitraClip ile yapılmış perkütan mitral kapak tamiri serisi: Tek merkez deneyimleri

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ABSTRACT

Objective: Mitral valve regurgitation (MR) is the second most common heart valve disease in Europe. Without intervention, prognosis of severe symptomatic MR is poor. Percutaneous edge-to-edge mitral valve repair with MitraClip is a promising mitral regurgitation treatment technique in select, high-surgical-risk patients. The present objective was to describe the experience of a single center with MitraClip use in a high-risk series in Turkey.

Methods: Between May 2013 and September 2014, 28 high-surgical-risk patients with MR of at least grade 3+ and mean EuroSCORE of 26% underwent MitraClip implantation at our institution. In-hospital and follow-up safety and efficacy results are presented.

Results: Mean patient age was 58 years, and 75% were male. Grade 3 or 4 MR was present in all patients, and was primarily the result of restrictive functional mitral regurgitation (in 89% of cases). Mean left ventricular ejection fraction (LVEF) was 27% and New York Heart Association (NYHA) classification was III or IV in 89% of the population. Acute procedural success was 89%, with 47% of patients receiving a single clip, 39% receiving 2 clips, and 14% receiving 3 clips. One periprocedural death occurred, and 2 deaths occurred during follow-up (mean: 13.9 months). After 1 year, more than 75% of patients had MR severity of ≤2+ and NYHA classification of I or II, but no significant change in left ventricular volume or systolic function. Significant improvement in 6-minute walk test and quality of life was also observed.

Conclusion: Initial experience with the MitraClip system showed promising results in patients considered high-surgical-risk, particularly in those with end-stage heart failure.

ÖZET

Amaç: Mitral kapak yetersizliği (MY) Avrupa'da ikinci en sık görülen kalp kapak hastalığıdır. Girişim yapılmaz ise ciddi semptomlu MY'nin prognozu kötüdür. Perkütan uc uca mitral kapak tamiri, MitraClip sistemi sayesinde yüksek cerrahi riske sahip MY'li hastalarda umut vaat etmektedir. Bu çalışmanın amacı yüksek cerrahi riskli olgularda MitraClip uygulamasının Türkiye'de tek merkeze ait sonuçlarını sunmaktır.

Yöntemler: Mayıs 2013 ile Eylül 2014 arasında, MY derecesi en az 3 olan ve ortalama EuroSCORE'u %26 bulunan, yüksek cerrahi riskli 28 hastaya merkezimizde MitraClip yerleştirildi. Hastane içi ve takipteki güvenlik ve etkinlik sonuçları sunuldu.

Bulgular: Hastaların ortalama yaşı 58 ve %75'i erkekti. Büyük bölümü (%89) restriktif fonksiyonel MY'den oluşan 3–4 derece MY tüm hastalarda mevcuttu. Ortalama sol ventrikül ejeksiyon fraksiyonu %27 olup hastaların %89'unda NYHA (New York Heart Association) fonksiyonel sınıf III–IV idi. Akut işlem başarısı %89 idi (hastaların %47'sine tek clip, %39'una iki clip ve %14'üne üç clip takılmıştır). Bir hasta işlem çevresi dönemde, iki hasta da takip (ortalama 13.9 ay) esnasında hayatını kaybetti. Ortalama bir yılın üzerindeki takip sonrası hastaların %75'inden fazlasının MY'si ≤2 ve NYHA sınıfı I-II idi. Bununla birlikte sol ventrikül hacmi ve sistolik fonksiyonlarında önemli bir değişiklik saptanmadı. Ayrıca yaşam kalite skorları ve altı dakika yürüme mesafelerinde önemli iyileşme gözlendi

Sonuç: MitraClip deneyimlerimizin sonuçları yüksek cerrahi riskli, özellikle son dönem kalp yetersizlikli hastalar için umut vericidir.



Mitral valve regurgitation (MR) is the second-most-frequent heart valve disease in Europe, accounting for 31.5% of valvular abnormality cases in adults. [11] Untreated MR causes increased morbidity and mortality in patients with primary or secondary MR. [1,2] Surgical intervention is recommended for symptomatic, severe MR, or asymptomatic, severe MR with left ventricular dysfunction or dilatation, based on current guideline criteria. [3] Although surgical repair is the best option for degenerative MR, in which the valve itself is diseased, results are less optimal in functional MR, which occurs secondary to left ventricular dilatation, stretching of the mitral annulus, and regional wall motion abnormality. [4]

However, in spite of improvements in surgical technique, perioperative morbidity and mortality continue to be a significant problem in high-risk patients with advanced age, multiple comorbidities, and advanced heart failure. As many as 49.0% of patients with MR and in need of repair or replacement are considered at high risk for surgical intervention, and are therefore not amenable to surgery.[7] For these reasons, the MitraClip device (Abbott Vascular, Inc., Santa Clara, CA, USA) was developed to achieve percutaneous repair of MR by approximating the middle scallops of the anterior and posterior mitral valve leaflets, mimicking the surgical repair achieved using a stitch (i.e., by Alfieri technique). Surgical mitral valve edge-to-edge repair to create a double orifice valve was first performed by Alfieri in the early 1990s.^[5] It is important to note that this technique offers better results when associated with ring annuloplasty, as later attested by Alfieri himself. [6] Over the last decade, incidence of interventional treatment of MR with MitraClip device has rapidly increased in Europe and America, following the completion of a safety and feasibility registry (EVEREST I) for the MitraClip system, [8,9] and a subsequent randomized, controlled EVEREST II trial in which results of MitraClip implantation were compared with those of surgery.[10] Successful MitraClip therapy has been suggested for effective improvement of functional and clinical outcome in inoperable or high-risk patients. It has been included in recently published European and American guidelines for consideration (Class 2b indication) when the heart team agrees that the patient is at high risk from surgery, and has functional and degenerative MR.[3,11]

Between May 2013 and December 2014, 28 patients underwent mitral clip implantation at our institution. Presently reported is the experience of a single

Abbreviations:

6MWT 6-minute walk test LVADLeft ventricular assist device LVEF Left ventricular ejection fraction MLHFO Minnesota Living with Heart Failure quality of life questionnaire MR Mitral valve regurgitation NYHA New York Heart Association TEETransesophageal echocardiography TTFTransthoracic echocardiography

center with percutaneous mitral valve repair using the Mitraclip in a high-risk series in Turkey.

METHODS

Patient population

The prospective registry included 28 consecutive patients treated with the MitraClip system in our institution between May 2013 and December 2014. Criteria for selection included at least moderate-to-severe MR with heart failure symptoms and suitable echocardiographic parameters for MitraClip implantation. All patients considered were assessed by the heart team, which included a cardiologist specializing in echocardiography and valvular disease, an interventional cardiologist, a cardiac surgeon, and an anesthesiologist. Patients underwent transesophageal echocardiography (TEE), and the images were reviewed by a committee of external experts from Abbott Vascular, Inc. The heart team were in agreement that percutaneous treatment should be performed because the risk of surgery was unreasonably high in each patient, and that each had favorable anatomy suitable for clip implantation. Two procedures were performed following major cardiovascular surgery as a "bailout" from a prolonged intubated postoperative period. MR was graded by color Doppler and by assessment of the width of the vena contracta. Mitral regurgitant fraction was calculated using proximal isovelocity surface area and MR velocity-time integral, according to current guidelines,[12,13] and was classified as mild (1+), mild-to-moderate (2+), moderate-to-severe (3+), or severe (4+). Anatomical inclusion criteria for Mitra-Clip implantation were MR originating from the A2-P2 area, coaptation length >2 mm, coaptation depth <11 mm, flail gap <10 mm, flail width <15 mm, mitral valve orifice area >4 cm², mobile leaflet length >1 cm, and absence of leaflet or excessive annular calcification. EVEREST II anatomic parameters were used. However, anatomic criteria were not applied in about 50% of patients with functional mitral regurgitation. ^[10] Consent was obtained following thorough oral and written explanation, the study was conducted in accordance with the Declaration of Helsinki, and the protocol was approved by the local ethics committee.

Standard diagnostic workup was conducted, including physical examination, and New York Heart Association functional capacity assessment (NYHA classification). In addition, patients answered the Minnesota Living with Heart Failure quality of life questionnaire (MLHFQ) and underwent 6-minute walk test (6MWT), electrocardiograms, blood tests, transthoracic echocardiography (TTE), TEE, and coronary angiography if indicated.

Echocardiography

TEE (at baseline) and TTE (at baseline and follow-up) were performed by experienced operators. Examinations were conducted using a Philips iE33 ultrasound system (Philips Healthcare, Inc., Bothell, WA, USA) equipped with an S5-1 transthoracic probe and an X7-2 transesophageal probe. Three cardiac cycles were stored in a cine loop for offline analysis. Left ventricular end-diastolic and end-systolic volumes, and left ventricular ejection fraction (LVEF) were calculated using Simpson's biplane method. Left ventricular end-diastolic and end-systolic diameters were obtained using 2-dimensional or M-mode echocardiography.

Procedure

The MitraClip system percutaneously creates a double mitral valve orifice, similar to the Alfieri stitch.^[5] The implantation procedure, which has been previously described,^[9] is performed using a 24-F MitraClip device.

All implantations were performed in a catheterization laboratory or hybrid room under general anesthesia. Fluoroscopy and 3-dimensional TEE were systematically used throughout the procedure, as described in the EVEREST II trial. Following transseptal puncture using standard technique, heparin was administered to achieve an activated clotting time of 250–300 seconds. After adequate grasping of the leaflets had been confirmed, defined as limited leaflet mobility, relative to the tips of both clip arms, the arms were closed, and MR reduction was assessed. MR was graded by color Doppler. If necessary, the clip can be opened, the mitral leaflets released, and the clip repositioned. If reduction in MR was adequate, the clip

was deployed. In addition to MR assessment, valve gradients were checked prior to deployment, in order to ensure lack of significant mitral stenosis, defined as mean transvalvular gradient >5 mmHg. Acute procedure success was defined as reduction of mitral regurgitation to grade ≤2 on intraprocedural TEE following deployment. More than 1 clip was implanted if suboptimal MR reduction was achieved with a single clip.

Definition and follow-up

Hospitalization duration was recorded, as were inhospital course and complications. All patients were prescribed aspirin 100 mg daily for life and clopidogrel 75 mg daily for 3 months. Prior to discharge, all patients underwent TTE to assess clip position and residual MR, as described. Safety and efficacy of the procedure were evaluated and described during in-hospital and follow-up periods. NYHA functional classification and 6MWT distance, in meters, were recorded at baseline and subsequent follow-up. Heart-failure-specific quality of life was assessed using the MLHFQ, [14] on which a lower score indicates better quality of life. Unplanned admission for heart failure was defined as hospitalization for treatment or overnight admission to the emergency room.

On follow-up at the cardiology clinic, patients were evaluated for clinical and echocardiographic examination, including MR severity, LV dimension and function, and pulmonary pressure. Heart transplantation, left ventricular assist device (LVAD) implantation, re-intervention, and any-cause mortality were considered the combined end point during follow-up.

Statistical analysis

Categorical variables are presented as count and percentage. Continuous variables are presented as mean (SD) or median (min–max), where appropriate. Continuous variables were compared using paired sample t-test or Wilcoxon signed-rank test, after checking for normalcy of distribution, which was assessed using Shapiro-Wilk test. A 2-tailed p value of <0.05 was considered statistically significant. Data analysis was performed using SPSS software (version 20.0; SPSS Inc., Chicago, IL, USA).

RESULTS

Patient characteristics

Twenty-eight patients (mean age 58.2±11.96 years, 7

females) underwent mitral valve repair with the MitraClip device at our center between May 2013 and December 2014. Etiology of mitral regurgitation was functional in 89% (25) of recipients, degenerative in 7% (2), and mixed in 4% (1). Mitral regurgitation was grade 4 in 68% (19) of patients and grade 3 in 32% (9), while 89% (25) of patients had severe heart failure symptoms (NYHA classification III or IV). Mean logistic EuroSCORE was 23.3% (9.0-70.2%). Mean number of hospitalizations for congestive heart failure in the 6 months prior to the procedure was 8.6±12.44 per patient, in spite of optimal medical treatment. Demographic data are shown in Table 1. A total of 46% of patients had coronary artery disease, while 46% had hypertension. The majority of patients received optimal medical treatment, with angiotensin-converting-enzyme inhibitors and/or angiotensin-receptor blockers and/or beta-blockers and/or diuretics, including aldosterone-blocking agents.

Procedural and in-hospital outcomes

Successful clip implantation was achieved in 93.4% (28) of cases. In 2 patients, clip could not be implanted due to inability to achieve transseptal puncture subsequently in the right atrial thrombus in 1 patient, and due to a device-related complication in the other. A total of 47% (13) patients received a single clip, 39% (11) received 2 clips, and 4 patients received 3 clips. Reduction of MR severity from grade 3 or 4 to ≤2 was achieved in 25 patients (89%) following implantation. Mean procedure duration was 189.4±81.35 minutes (range: 90.0-400.0 min). Median clip time was reduced from 222 minutes in the first 14 procedures to 157 minutes in the latter 14 procedures (p=0.030). Patients were discharged at a mean of 6.7±7.24 days, and mean intensive care unit stay was 1.7±1.72 days.

In-hospital death occurred in 3 patients, 2 of whom could not have been extubated following cardiovascular surgery. One of these patients had undergone sutureless aortic valve implantation and 2-vessel coronary artery bypass graft, and experienced mitral chordal rupture in the postoperative period. The patient could not be extubated and died in spite of successful MitraClip procedure. The second patient underwent left internal mammary artery-to-left anterior descending artery bypass graft on the beating heart, and could be extubated after MitraClip procedure, but died from unexplained secondary

Table 1. Baseline characteristics				
Characteristic	n=28			
Age, years (mean±SD)	58.2±11.96			
Female, n (%)	7 (25)			
Diabetes, n (%)	5 (18)			
Hypertension, n (%)	13 (46)			
Chronic renal failure, n(%)	4 (14)			
Chronic lung disease, n (%)	4 (14)			
Previous CVA, n (%)	1 (3.6)			
Ischemic heart disease, n (%)	13 (46)			
Previous CABG, n (%)	5 (18)			
Previous PCI, n (%)	8 (29)			
Previous MI, n (%)	12 (43)			
Atrial fibrillation, n (%)	4 (14)			
ICD/CRTD, n (%)	7 (25)			
Euroscore median (minmax.)	23.3 (9.0–70.2)			
Mitral regurgitation grade, n (%)				
II	0			
III	9 (32)			
IV	19 (68)			
Mitral regurgitation etiology, n (%)				
Functional	25 (89)			
Degenerative	2 (7)			
Mixed	1 (4)			
NYHA III/IV, n (%)				
II .	3 (11)			
III	7 (25)			
IV	18 (64)			
LVEF, % median (minmax.)	26.8 (14.2–72.7)			
Mean hospitalizations in previous	8.6±12.44			
6 months (mean±SD)				
Previous medications, n (%)				
ACE inhibitors/ARB	22 (79)			
Beta-blocker	24 (86)			
Loop diuretic	25 (89)			
Aldesterone antagonist	17 (61)			

SD: Standard deviation; ACE: Angiotensin converting enzyme; ARB: Angiotensin receptor blocker; CABG: Coronary artery bypass surgery; CVA: Cerebrovascular accident; ICD/CRTD: Implantable cardioverter defibrillator/cardiac resynchronization therapy device; LVEF: Left ventricular ejection fraction; MI: Myocardial infarction; NYHA: New York Heart Association; PCI: Percutaneous coronary intervention.

acute cardiovascular collapse. These deaths did not reflect experience with the MitraClip implantation procedure.

Table 2. Periprocedural complications outcomes during hospitalization	and	clinical
Characteristic	n	%
Death	1	3.8
Myocardial infarction	0	0
Reoperation	0	0
Stroke	1	3.8
Renal failure	1	3.8
Hospital infection	2	7.7
Transfusion ≥2 units blood	2	7.7
Mechanical ventilation >48h post-op	1	3.8
Tamponade/pericardiocentesis	2	7.7
Intestinal bleeding	0	0

However, the third death was related to the procedure. The patient experienced secondary cardiac tamponade at the seventh hour postprocedure, in spite of percutaneous drainage of effusion. Secondary cardiac tamponade was also experienced in the first day and treated with percutaneous drainage in another patient, without the need for surgery. Acute kidney injury and trans-ischemic attack occurred in same patient, but symptoms were in regression. Other in-hospital events were acute febrile respiratory illness in 2 patients, treated with antibiotic therapy. No myocardial infarction or need for prolonged mechanical ventilation was observed (Table 2).

Follow-up data

Mean and median follow-up durations were 13.9 and 12.0 months, respectively (range: 1.0–24.0 months). Of the 28 patients with successful clip implantation, follow-up data was collected for 25 (89%). During follow-up, 2 deaths occurred, both cardiac in origin, at 8 and 13 months post-implantation. Two patients received heart transplants, and LVAD was inserted in another. In 2 cases, partial clip detachment was observed. The first was treated successfully with a mitral mechanical valve. In the second patient, 1 of the 3 clips implanted had detached. He was medically followed. In addition, ischemic cerebral events were observed in 2 patients.

Mean number of hospitalizations for post-procedure congestive heart failure was 2.0 ± 2.60 per patient (range: 0–10.0) during follow-up. Functional classification was improved by at least 1 class in 17 of 19 patients (in 15 of whom it improved by ≥ 2 classes).

Eighteen of 26 patients had NYHA classification I or II at follow-up. One patient's NYHA classification was III (Figure 1). There was statistically significant improvement in follow-up 6MWT from baseline (210.0 [100.0–450.0] meters to 300.0 [150.0–450.0] meters, p=0.010; Figure 2). There was also significant improvement in follow-up MLHFQ score from baseline (56.0 [16.0–97.0] to 35.0 [15.0–60.0], p<0.001; Figure 3).

Echocardiography

Nineteen patients without combined end point underwent echocardiography at the end of a median 15.5±6.10 months follow-up (range: 7.0–24.0 months). Fifteen of these patients (79%) had reduction in MR grade to ≤2. The remaining 3 had MR grade 3 (Figure 4). At follow-up after MitraClip pro-

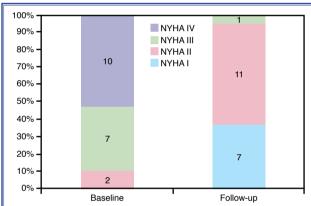


Figure 1. New York Heart Association (NYHA) classification at baseline and follow-up.

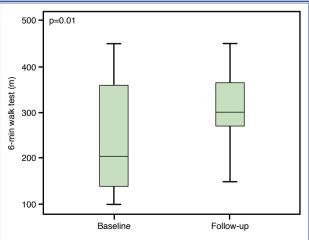


Figure 2. Mitral regurgitation (MR) grade at baseline and follow-up.

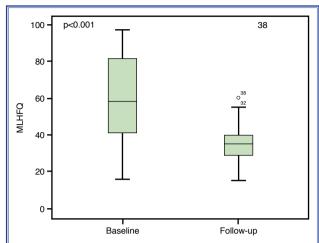


Figure 3. Comparison of baseline and follow-up Minnesota Living with Heart Failure quality of life questionnaire (ML-HFQ) score.

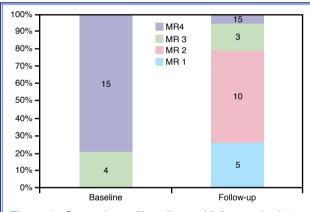


Figure 4. Comparison of baseline and follow-up 6-minute walk test.

cedure, there was no statistically significant change in LVEF (p=0.334). Left ventricular diameters and volumes were also slightly and non-significantly reduced (Table 3).

DISCUSSION

Presently reported were the experiences of a single center with Mitraclip percutaneous mitral valve repair in a high-risk series in Turkey. Included patients, most of whom were considered inoperable for mitral valve surgery, demonstrated a marked and consistent reduction in MR and improvement in quality of life, symptoms of heart failure, and exercise tolerance, after a median follow-up interval of more than 12 months. This initial experience with the MitraClip encouraged us to proceed with the procedure at our center.

Open mitral valve replacement or repair is still generally considered the standard treatment for symptomatic patients with significant MR.^[3,11] Without intervention, the prognosis of severe symptomatic MR is poor.^[2] The minimally invasive nature of the MitraClip, which was first introduced as a percutaneous intervention for MR in 2004,^[15] makes it a good option for patients unfit for surgery due to multiple comorbidities such as severe LV dysfunction and prior surgery.

EVEREST II was a randomized comparison of percutaneous mitral repair and mitral valve surgery that demonstrated device safety and lower complication rates of MitraClip procedures, though open surgery was deemed significantly more efficacious at 12 and 24 months. The majority of the 279 patients enrolled (73.0%) had degenerative MR, and all were suitable for surgical therapy, allowing them to be randomized 2:1 for MitraClip or surgery (repair was conducted in 86.0% of the population, replacement in the remaining 16.0%).^[8,10,16] The patient profile of the EVEREST II study, which was mainly organic, is radically different from that of European registries,^[17,18] and included a higher-risk population, with lower functional

Characteristic	Baseline (n=19)	Follow-up (n=19)	р
LVEF, % median (minmax.)	27.6 (14.1–73.2)	27.7 (16.4–67.0)	=0.334**
LVEDV, mL (mean±SD)	242.2±84.23	241.7±84.89	=0.805*
LVESV, mL median (minmax.)	175.0 (25.3–358.6)	174.5 (31.7–365.4)	=0.840**
LVEDD, mm median (minmax.)	71.0 (49.1–88.4)	71.0 (48.6–88.6)	=0.096**
LVESD, mm median (minmax.)	62.0 (32.5-80.3)	62.0 (33.9–79.5)	=0.739**

Difference between groups by *paired sample t-test, or **Wilcoxon signed rank test.

LVEF: Left ventricular ejection fraction; LVEDV: Left ventricular end-diastolic volume; SD: Standard deviation; LVESV: Left ventricular end-systolic volume; LVEDD: Left ventricular end-diastolic diameter; LVESD: Left ventricular end-systolic diameter.

capacity and a higher rate of reduced LV function, together with mostly functional MR etiology. The present population exhibited a high EuroSCORE (23.3% [9.0–70.2%]), and its rate of secondary MR (89.0%) corresponded to current indications in Europe.

Two unsuccessful clip implantations occurred. One was related to the MitraClip device. [19] The present results are comparable to those reported by more experienced centers, regarding rates of successful clip implantation. [20,21] The other unsuccessful clip implantation was caused by transseptal puncture. In addition, pericardial tamponade was observed in 2 patients in the first 12 hours after the procedure. One such patient was successfully treated with percutaneous drainage, but the other died in spite of successful drainage. We believe that pericardial tamponade may have been caused by the very large size of the heart chambers and atrial septum deviation toward the right, due to excess left atrial pressure, resulting in prolonged and difficult transseptal puncture. However, rates of acute procedural success and in-hospital mortality were 89.0% and 3.8%, respectively, comparable to those of a recent systematic review of high-risk patients who underwent MitraClip implantation, in which inhospital mortality ranged from 0-7.8%, and acute MR reduction ranged from 72.0–100%.[22]

Over the 12 months of follow-up, the mortality rate was 11.5% in our cohort, which compares well with the 15.0–25.0% rate reported in both relevant European studies. [17,18] During follow-up, combined primary endpoint (all-cause mortality, transplantation, LVAD implantation, and conventional mitral valve surgery) was relatively high in the present series (27.0%)—likely the result of clinical and echocardiographic characteristics; most patients had functional MR (92.0%), very large left heart size, and low ejection fraction percentage. However, Neuss at al. reported a combined end point of 32.0% in a large cohort with a similar patient profile. [23]

The main goal of MitraClip procedure in high-risk patients is to improve symptoms by reducing MR. After 1 year, more than 75.0% of patients had MR severity of ≤2+ and NYHA classification I or II, results similar to those of other studies, in which heart failure symptoms were reportedly ameliorated in 64.0–77.0% of patients, and durable MR reduction was reported in 64.0–87.0% of patients. [17,20,24] In addition to improvement in NYHA functional classification,

objective outcomes including MLHFQ and 6MWT continued to improve throughout follow-up. Quantitatively evaluated improvement following treatment was reported in several studies with high-risk populations. [24-26] Mean number of hospitalizations for congestive heart failure in the 6 months prior to the procedure was 8.6±12.44 per patient in the present series, in spite of optimal medical treatment. Over the 12 months of follow-up, this was reduced to 2.0±2.60 hospitalizations per patient, a finding in accordance with those of others. [24]

The present improvement in procedure time was in accordance with the learning curve reported in several studies. Median clip time was presently reduced from 222 minutes in the first 14 procedures to 157 minutes in the latter 14 (p=0.030). In accordance with previous findings, [27] a discrepancy was observed between residual mitral regurgitation measured in the catheterization laboratory immediately after implantation, with the patient under anesthesia, and that measured at discharge; MR increased by at least 1 degree in approximately 7 patients. This may have been caused by substantially reduced systemic vascular resistance due to the anesthetic agent. It is important to keep in mind the lowering effect of general anesthesia on MR degree.

Remodeling of the left ventricle following percutaneous mitral repair on echocardiography during follow-up was demonstrated in a number of studies. [10,24,28] However, in high-risk cohorts, which primarily included end-stage heart failure patients, LV volume and diameter reduction were not statistically significant. [17,18] Similar to that of other high-risk cohorts, the lack of significant cardiac remodeling may have in part been reflective of the advanced state of disease in the present population.

In conclusion, MitraClip implantation can be performed in high-risk cohorts in Turkey with mainly functional MR; results compared favorably with those of international cohorts. Preliminary outcomes regarding safety and efficacy are encouraging, and MitraClip implantation may be a viable solution to the problem faced by patients without surgical options.

Conflict-of-interest issues regarding the authorship or article: None declared

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