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Valvuloplastie mitrale percutanée par système MitraClip : expérience lausannoise

Experience of transcatheter mitral-valve repair in Lausanne

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ABSTRACT

INTRODUCTION

Symptomatic mitral regurgitation patients have a poor prognosis unless treated by surgery. 49% of them are ineligible for surgical treatment due to contraindications or judged at high surgical risk by an interdisciplinary heart team and are left untreated. Percutaneous treatment with the MitraClip device is an alternative option for selected patients and has been proven to be safe and effective. The aim of this study is to describe our institution's early results with implantation of the MitraClip and to compare them with other registries.

METHODS

A retrospective observational study was performed in the University Hospital of Lausanne. All patients treated with MitraClip in our institution between December 2012 and August 2018 were included in the study. Primary outcomes were all-cause mortality or unplanned hospitalization for heart failure at 2-years and overall improvement in New York Heart Association functional class. Secondary outcomes included reduction in mitral regurgitation grade, change in left ventricular ejection fraction, periprocedural complications and adverse event within one month.

RESULTS

A total of 75 patients (72% men) underwent the Mitraclip implantation, mainly for functional mitral regurgitation (57%) of grade 3+ or 4+ (97%) with mean left ventricular ejection fraction of 44% and New York Heart Association functional class III or IV (73%). Acute device implantation was successful in 87% of cases. Periprocedural complications occurred in 24% of patients (3 patients with ischemic stroke and 1 patient had a cardiac tamponade). At the time of discharge, there was an improvement in the New York Heart Association functional class ($p<0.0001$) with 51% of reduction of at least one functional class and 90% of patients had mitral regurgitation ≤ 2+ ($p<0.0001$). Left ventricular ejection fraction was not significantly different than baseline ($p=0.48$). In the first month post-implantation follow-up, complications occurred in 14% of patients (1 patient died at 11 days after a hemorrhagic stroke and 1 patient had an ischemic stroke). Within 2-year, all-cause mortality was 28% with 85% of non-cardiac cause, 24% needed readmission for heart failure and 4.0% had a mitral valve surgery.

CONCLUSION

In the University Hospital of Lausanne, the MitraClip procedure for patients with mitral regurgitation and at high surgical risk is a safe and effective alternative facilitating the reduction of mitral regurgitation and improving functional capacity. Primary and secondary outcomes are similar to those observed in other registries (ACCESS-EU study, TCVT registry and TRAMI registry).

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INTRODUCTION

Mitral regurgitation (MR) is the second most frequent valvular heart disease in the developed countries (1). Its prevalence in the United States population is 1.7% and increases with age to reach 9.3% of people over 75 years old (2).

MR results in a lack of coaptation between anterior and posterior leaflets of the mitral valve during systole, allowing the blood to flow back in the left atrium instead of flowing from the left ventricle through the aortic valve (3). The European Society of Cardiology (ESC) has issued guidelines that classify the origin of MR as either primary (degenerative), when one or several components of the valve apparatus are directly affected or secondary (functional), when remodeling occurs in the left ventricle due to ischemic or dilated cardiomyopathy (4).

Leakage increase blood volume and pressure in the left atrium that tends to enlarge and may develop atrial fibrillation. If regurgitation is severe, blood volume and pressure increase in pulmonary veins, lungs and right heart and can lead to lungs congestion or heart failure with associated symptoms (dyspnea, shortness of breath at night or during exercise, fatigue, edema in the legs or ankles, decrease in appetite, cough…). In some case, patients, may be asymptomatic for years, despite severe regurgitation.

Severe symptomatic MR without surgical treatment is associated with 5% of mortality per year and reach 60% at 5 year if associated with heart failure (5). There are no medications indicated to treat MR, but some are used to manage symptoms of heart failure or rhythm abnormalities (4). Surgical treatment (mitral valve repair or replacement) is the primary treatment for severe MR and/or symptomatic patients. Nevertheless, 49% symptomatic patients with severe MR are not eligible for surgery due to advanced age, left ventricular dysfunction or comorbidities (6).

Edge-to-edge leaflet repair technique, developed by Alfieri in the early 1990s, is a surgery that consists in suturing between the anterior and posterior leaflet to create a double-orifice valve during diastole and a better approximation of the leaflets during systole, thereby reducing the MR (7). Based on this technique, a percutaneous device, the MitraClip (Abbott, Menlo Park, CA, USA) has been developed and is an alternative to surgery for patients at high surgical risk (8).

The EVEREST I trial (Endovascular Valve Edge-to-Edge Repair Study) demonstrated the feasibility and the safety of this treatment (9) and the EVEREST II trial, a multicenter randomized controlled trial which compared percutaneous repair versus surgery in operable patients, proved its efficacy (10). The device has been approved in Europe under the CE mark since 2008 and by the US FDA in 2012. Since then, several studies established that there is a low incidence of mortality and hospitalization for heart failure and significant improvements in functional status (11). ESC 2017 guidelines recommend the percutaneous edge-to-edge repair in patients with symptomatic degenerative MR who are at high surgical risk or inoperable and have been discussed by a heart team (class IIB), while in patients with functional MR and left ventricular ejection fraction < 30% who remain symptomatic despite optimal medical management, conservative (medical therapy) or palliative (catheter-based and surgery) treatment is evaluated by a heart team (class IIB)(4).

Introduced in 2012 in the University Hospital of Lausanne, this technique is currently the only alternative to non-eligible patients for a mitral surgery.

Objectives are to describe our institution's early results with implantation of the MitraClip and to compare them with other registries.

METHODS

Study design

A retrospective observational study (category A) was performed in the University Hospital of Lausanne. All patients treated with MitraClip in our institution between December 2012 and August 2018 were included in the study. Demographic information, preoperative evaluation, intraoperative and postoperative data about each patient were collected until October 2018 to create a database.

Patient selection

Patients with symptomatic grade 3+ or greater MR despite optimal therapy, referred to our institution for consideration of MitraClip implantation were discussed by a heart team including surgeons, interventional cardiologists and imaging specialists to decide the optimal treatment for each patient. All of them classified as being at high risk to undergo a mitral surgery were candidates for device implantation. An initial evaluation that included a transthoracic echocardiography (TTE) and a transesophageal echocardiography (TEE) was performed to quantify MR and to characterize anatomic feasibility of MitraClip implantation.

Operative procedure

The MitraClip procedure is performed under general anesthesia and with echocardiographic and fluoroscopic guidance. After establishing a femoral venous access, an atrial transseptal puncture is performed in the upper portion of the fossa ovalis, 4-5 cm above the valve coaptation line, and a 24-Fr steerable guide is passed into the left atrium. The clip delivery system is advanced through the guide to introduce the MitraClip in the left atrium. The MitraClip is positioned with arms perpendicular to the line of coaptation of the valve leaflets and advanced into the left ventricle with arms opened to 120°. Then, the MitraClip is gradually pulled back towards the left atrium grasping the leaflets and closed to 20°. TEE is performed to ensure that both leaflets are appropriately inserted and secure within the clip and to analyze the MR reduction and pressure gradients. Once the assessments are positive, the clip arms are closed. Additional clips may be placed to optimize MR reduction if there was no residual mitral stenosis. At the end of the procedure, the system is withdrawn and antiplatelet therapy is instituted.

Outcomes and definition of variables

Primary outcomes of interest were all-cause mortality or unplanned hospitalization for heart failure at 2-years and overall improvement in New York Heart Association (NYHA) functional class after implantation. Unplanned hospitalization for heart failure included all admissions in the emergency department or hospitalizations in a medical/cardiologic unit for the treatment of all cause heart failure. NYHA functional class was used to assess subjectively the patient's functional capacity. Secondary outcomes included reduction in MR grade, change in left ventricular ejection fraction (LVEF), periprocedural complications and adverse event within one month. MR grade is classified in 1+ (mild), 2+ (moderate), 3+ (moderate-to-severe) and 4+ (severe) using a transthoracic echocardiography according to American Society of Echocardiography recommendations. Acute device success was defined as residual MR ≤ 2+ after clip implantation and minimum 1 clip implanted.

Statistical analysis

Data analysis was done using Microsoft Excel (version 16.17). Categoric variables are expressed as percentages. Continuous variables are presented as mean ± standard deviation or as median (interquartile range, IQ25, IQ75). The Student's unpaired t test was used to compare continuous variables. Kaplan-Meier curves were constructed to study survival and absence of hospitalizations for heart failure. P value < 0.05 were considered significant.

Ethical considerations

The project was approved by the Cantonal (VD) Ethic Committee on research involving humans and was conducted in accordance with the Declaration of Helsinki. All participants signed informed consent.

RESULTS

Patient characteristics

From December 11, 2012, through August 3, 2018, a total of 75 patients underwent Mitraclip implantation. The baseline characteristics of all patients are shown in Table 1.

The mean age of the study population was 77 ± 10 years, 42% of the patients were aged 80 years or more. 90% of patients presented at least one comorbidity and 92% had cardio-vascular risk factors. The mean logistic EuroSCORE II (European System for Cardiac Operative Risk Evaluation) at baseline, which allows the calculation of the risk of death after a heart operation, was 6.1 ± 4.4%.

The majority of the patients had severe symptoms of heart failure, with 73% in NYHA functional class III or IV. The mean LVEF was 44 ± 16%, with 22% of patients with LVEF < 30%, 42% of patients between 30-50% and 36% with LVEF > 50%. Etiology of regurgitation was functional in 57% of patients and degenerative in 30%. In 13% the etiology was mixed. MR grade was ≥ 3+ in 97% of the patients.

Table 1. Characteristics of the Patients at Baseline

Characteristics	CHUV, Lausanne
Clinical [1]	
Age, yr	77 ± 10
Male sex, %	72
Diabetes, %	19
Hypertension, %	77
Hypercholesterolemia, %	50
Body-mass index [2], kg/m2	25 ± 4.5
Previous percutaneous coronary intervention, %	45
Previous coronary-artery bypass grafting, %	18
Previous stroke or transient ischemic attack, %	12
Peripheral vascular disease, %	13
History of atrial fibrillation or flutter, %	50
Previous implantation of pacemaker/defibrillator, %	19
Chronic obstructive pulmonary disease, %	19
Obstructive sleep apnea syndrome, %	13
Kidney failure, %	31
EuroSCORE II [3], %	6.1 ± 4.4
Related to heart failure [4]	
NYHA class, % (no./total no.)	
I	1.3 (1/77)
II	26 (20/77)
III	64 (49/77)
IV	9.1 (7/77)
Echocardiographic data [4]	
Left ventricular ejection fraction, %	44 ± 16
Mechanism of mitral regurgitation, % (no./total no.)	
Functional	57 (44/77)
Degenerative	30 (23/77)
Mixed	13 (10/77)
Severity of mitral regurgitation, % (no./total no.)	
grade 2+ to 3+	2.6 (2/77)

grade 3+	16 (12/77)
grade 3+ to 4+	3.9 (3/77)
grade 4+	78 (60/77)
Effective regurgitant orifice area, mm2	45 ± 23

[1] 75 patients underwent MitraClip implantation and 78 device implantations were attempted. Therefore, 78 patients' data in total were considerate. Plus-minus values are mean ± SD. NYHA = New York Heart Association.
[2] The body-mass index is the weight in kilograms divided by the square of the height in meters.
[3] European System for Cardiac Operative Risk Evaluation (EuroSCORE) which allows the calculation of the risk of death after a heart operation, range from 0 to 100% with higher percentages indicating greater risk.
[4] One patient had a tricuspid regurgitation in whom MitraClip was attempted. His clinical data were included in the statistical analysis but those related to heart failure, echocardiographic data and follow-up were not included.

Data on the procedure

A total of 78 device implantations were attempted. On average, procedural time was 154 ± 63 minutes, radiation time 44 ± 23 minutes, and 1.6 ± 0.7 clips were implanted. One clip was implanted in 45% of cases, 2 clips were implanted in the majority of cases (47%) and a few patients received 3 or more clips (5.1%). 2 patients (2.6%) had no clip implanted, one patient had an abdominal venous perforation with transseptal puncture needle at the beginning of the procedure resulting in a hemoperitoneum without active bleeding seen on the CT scan after the procedure and one because the clip made a trans-mitral gradient of 8 mmHg, resulting in a mitral stenosis. A MitraClip was attempted in a patient with tricuspid regurgitation but failed because of a persistent regurgitation despite four clips which made a transaortic gradient of 20 mmHg. Among the 77 patients in whom echocardiography was performed after the clip implantation, MR grade was 1+ in 32 patients (42%), grade 1+ to 2+ in 20 patients (26%), grade 2+ in 17 patients (22%), grade 2+ to 3+ in 3 patients (3.9%), grade 3+ in 2 patients (2.6%) and grade 4+ in 3 patients (3.9%) (Figure 1), which was a significantly improvement compared with baseline (p<0.0001).

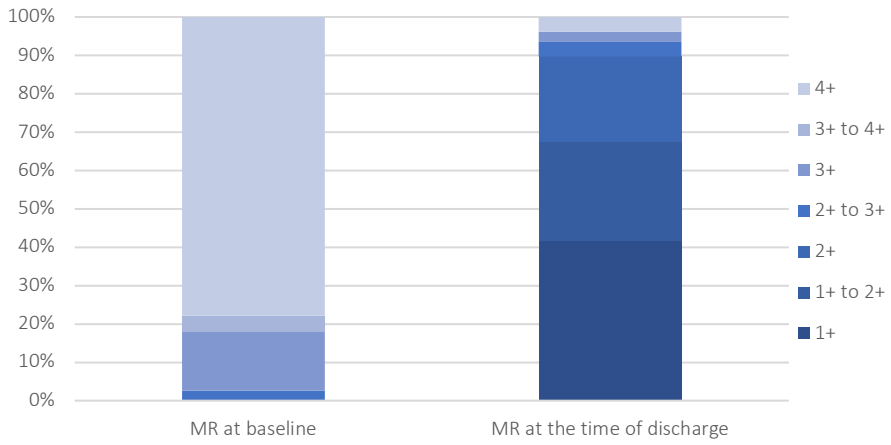

Figure 1. Mitral regurgitation at baseline and at the time of discharge

Acute device implantation, defined as residual MR ≤ 2+ after MitraClip implantation and minimum 1 clip implanted, was successful in 87% of cases. 19 patients of the 78 procedures (24%) had periprocedural complications (Table 2). 4 patients had potentially severe complications during procedure; 3 patients had an ischemic stroke, 2 with full recovery at the time of discharge from hospital, and one patient required a pericardiocentesis due to cardiac tamponade that occurred during transseptal puncture without needing cardiac surgery. 6 patients had atrial septum defect with bidirectional shunt between both atriums that required a closure device. 2 patients had intestinal lesions as a result of transesophageal echocardiography that needed gastroscopy after the procedure; one patient had bleeding of cardia with 5 clips needed to control the bleeding and the other one had esophagus hematoma. Partial detachment of the clip that grasped only on one leaflet occurred in one patient. This

patient had no embolization of the clip after the hospitalization. No cases of death and no patients required urgent heart surgery 24-hours after MitraClip implantation.

Table 2. Periprocedural Complications and Adverse Events within 1 Month

Variable	CHUV, Lausanne
Periprocedural complications during device implantation, no./total no.[1] (%)	
Device-implantation failure	2/78 (2.6)
Death	0/78 (0)
Stroke	3/78 (3.8)
Tamponade/pericardiocentesis	1/78 (1.3)
Urgent conversion to heart surgery	0/78 (0)
Hemorrhage resulting in transfusion [2]	2/78 (2.6)
New-onset atrial fibrillation	0/78 (0)
Deep venous thrombosis at the femoral venous access	1/78 (1.3)
Atrial septum lesion or atrial septal defect	6/78 (7.7)
Partial detachment of the clip	1/78 (1.3)
Gas embolism in coronary artery	1/78 (1.3)
Intestinal lesion	2/78 (2.6)
Adverse Events within 1 month after device implantation, no./total no.[3] (%)	
Death	1/74 (1.3)
Stroke	2/74 (2.7)
Heart surgery	0/74 (0)
Hemorrhage resulting in transfusion	0/74 (0)
New-onset cardiac rhythm abnormalities	4/74 (5.4)
Respiratory infection	3/74 (4.0)
Partial detachment of the clip	1/74 (1.3)

[1] 78 represents the number of patients in whom device implantation was attempted.
[2] Hemorrhage that required blood transfusion (more than two units of packed red blood cells).
[3] Adverse events data of 74 patients were available within one month.

Follow-up data

At the time of discharge from hospital, assessments of the functional capacity were available for 45 patients (Figure 2). Of these patients, 23 (51%) had a reduction in NYHA functional class; 8 patients (18%) had NYHA functional class I, 19 (42%) NYHA functional class II, 17 (38%) NYHA functional class III and 1 (2.2%) NYHA functional class IV, which was significantly different from the previous values (mean NYHA functional class 2.24 ± 0.61 vs 2.81 ± 0.77 at baseline, $p<0.0001$). Left ventricular ejection fraction was 42 ± 16%, not significantly different than baseline (44 ± 16%, $p=0.48$).

During hospitalization and in the first month post-implantation follow-up, complications occurred in 10 patients (14%) of 74 patients (Table 2). One patient had a hemorrhagic stroke at 4 days after the procedure and died at 11 days and one patient had an ischemic stroke at 2 days. 3 patients had nosocomial pneumonia.

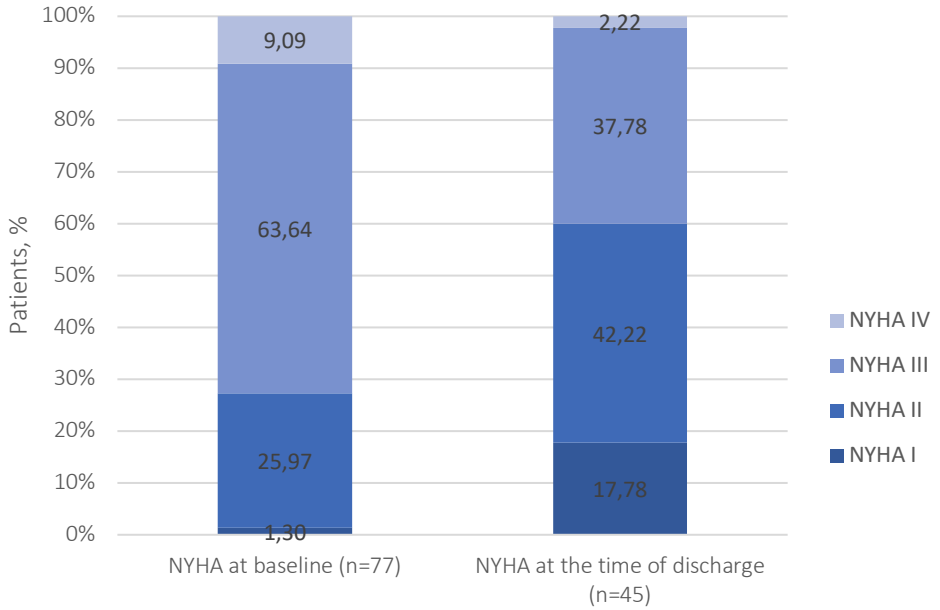

Figure 2. New York Heart Association (NYHA) functional class at baseline and at the time of discharge from hospital.

Clinical follow-up about mortality within 1-year was obtained in 57 patients with a follow-up rate of 98% (17 patients had not yet completed the 1-year follow-up) and the estimated 1-year mortality was 8.2%. At two years, 13 (28%) of 47 patients died, 11 (85%) of non-cardiac cause and 2 (15%) of a cardiac origin, on average during the thirteenth month (Figure 3). 11 (24%) of 45 patients needed readmission due to heart failure, which occurred, on average, in the fourth month (Figure 4). A total of 3 (4.0%) patients had to repeat MitraClip procedures after the first implantation, one patient at 17 days because of an abdominal venous perforation without clip implanted, one patient at 3 months because of a partial dehiscence at 9 days with a chordae tendineae rupture and one patient at 19 months because of an anterior leaflet tear. 3 (4.0%) of 75 patients underwent mitral valve repair or replacement after the MitraClip implant procedure.

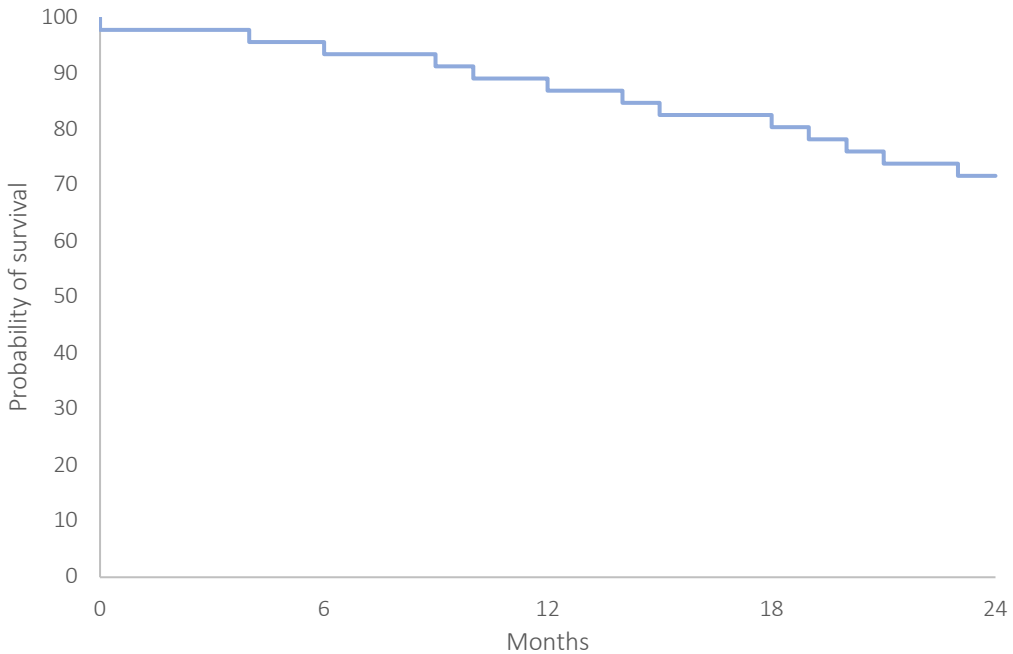

Figure 3. Kaplan-Meier curve estimates of survival at 24 months (n=47)

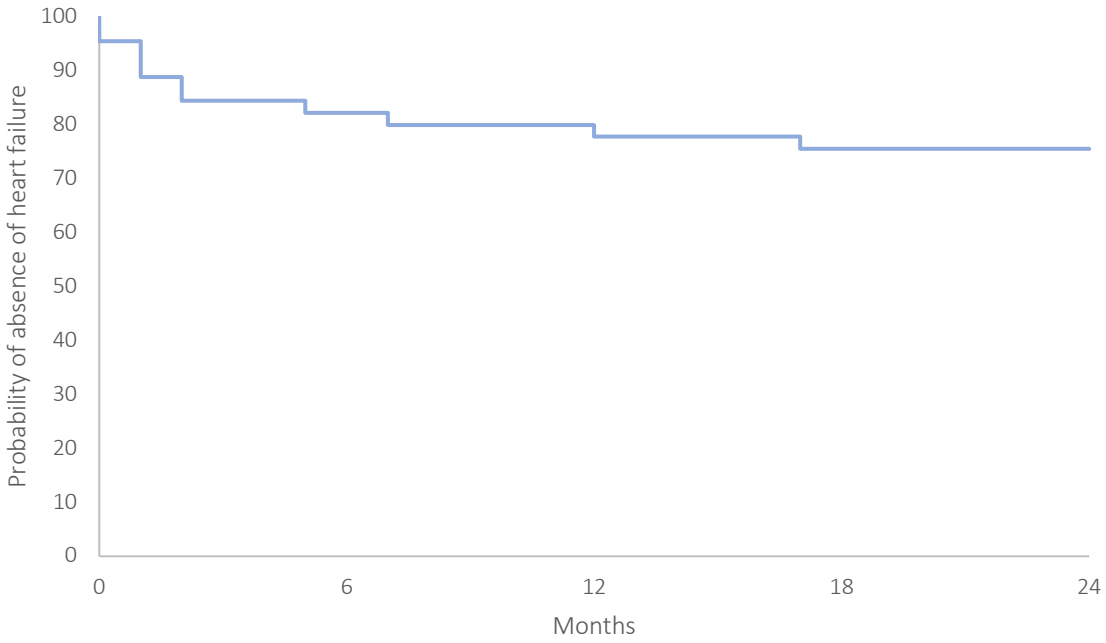

Figure 4. Kaplan-Meier curve estimates absence of unplanned hospitalization for heart failure at 24 months (n=45)

DISCUSSION

The aim of this study was to expose the University Hospital of Lausanne early results with implantation of MitraClip and compare them with results reported in registries. First, the high acute procedural success (87%), the rate of periprocedural complications (24%) and the 1-month incidence of all adverse event (14%) confirms that the MitraClip procedure is reasonably safe. Complete detachment or embolization of the clip were not reported. Furthermore, mortality within one year was 8.2% and within two years 28%, mostly (85%) related to non-cardiac causes, reflecting the patients' baseline comorbidities. Second, the reduction in MR grade ≤ 2+ (90%) and improvement in functional class in > 50% of patients proved the short term efficacity of MitraClip. In addition, about 75% patients that underwent a clip needed no readmission for heart failure at two years, which means that efficacity persists throughout the years.

In the following, results will be compared with the initial EVEREST II cohort (12) and the 3 largest series of MitraClip patients published so far: the ACCESS-EU (ACCESS-Europe, A Two-Phase Observational Study of the MitraClip System in Europe), a prospective non-randomized study that enrolled 567 patients in 14 centers in Germany, Italy and Denmark in 2013 (13), the Transcatheter Valve Treatment Sentinel Pilot Registry (TCVT registry), a prospective independent study that enrolled 628 patients treated in 25 centers in 8 European countries in 2014 (14) and the Transcatheter Mitral Valve Interventions (TRAMI registry), a prospective and retrospective non-randomized study that enrolled 828 patients in 21 German sites in 2015 (15).

Patients' demographics information and preoperative evaluation are very similar to those observed in registries (13)(14)(15). In concordance with these registries, our results show that patients who nowadays benefit from an implantation reflect a higher risk profile than those enrolled in the EVEREST II clinical trial (12). Patients included in our registry were older (mean age 77 ± 10 vs 67.0 ± 12.7 years), in more advanced stages of heart failure (NYHA functional class III or IV in 73% vs 50.0%), mainly with lower LVEF (44 ± 16 vs 59.9 ± 10.1%) and often with functional valve disease (57% vs 27.0%). While EVEREST II trial enrolled operable patients, patients receiving a MitraClip in reality are those judged ineligibles for surgery due to their high-risk level. Logistic EuroSCORE II was 6.1 ± 4.4%, lower than logistic EuroSCORE I observed in previous registries (ACCESS-EU 23.0 ± 18.3%, TCVT registry 20.4 ± 16.7%, TRAMI registry 20%). This finding may be explained by the fact that EuroSCORE II had better predictive discrimination for operative mortality than EuroSCORE I, which greatly overestimated this risk (16) and that other adverse factors, like oncological context or patients' fragility often seen in patients treated in our institution, were not taken into account in the risk score calculation.

Despite the higher risk at baseline, results of acute procedural success, with clip implantation rate (97% vs 96.0% in EVEREST II trial) and immediate achievement of MR grade 2+ or lower in 90% (71.8% in EVEREST II trial), are substantially better than those in the early EVEREST II involving patients at high risk of surgical mortality (10). Notably, acute procedural success was similar to contemporary registries (87% vs 91.2% in ACCESS-EU, 95.4% in TCVT registry and 94.0% in TRAMI registry). It reflects probably the operator's increased experience with implantation over time. Grasso and al. have examined the device implantation time and have demonstrated a learning curve in the overall experience (17). Even though this high acute procedural success rate is achieved, almost one quarter of patients remain highly symptomatic (NYHA functional class III or IV) at the time of discharge. Further research must identify which clinical or procedural characteristics are predictive of such a poor clinical response.

LVEF was not significantly different at the time of discharge from the hospital (42 ± 16% vs 44 ± 16% at baseline, p=0.48). MR is only one of the multiple mechanisms that lead to left ventricle dilatation in patients with functional MR, as most cases in this report, and may explained the reason of steady LVEF after implantation of the clip.

Periprocedural complications and adverse event within one month (respectively 24% and 14%) in our registry was higher than other publications, most likely driven by strictness of variables and definitions or by advanced age patients with a high burden of comorbidities. The incidence of specific

periprocedural complications was comparable with no case of dead (no case in ACCESS-EU, 0.1% in TRAMI registry), stroke rate of 3.8% (no case in ACCESS-EU) and cardiac tamponade rate of 1.3% (0.9% in ACCESS-EU, 1.1% in TCVT, 1.7% in TRAMI registry). The incidence of major adverse event within one month was also comparable with mortality of 1.3% (3.4% in ACCESS-EU, 2.9% in TCVT registry, 4.5% in TRAMI registry), stroke rate of 2.7% (0.7% in ACCESS-EU, 0.2% in TCVT registry, 0.8% in TRAMI registry).

One-year mortality was 8.2%, slightly lower than in ACCESS-EU (17.3%), TCVT registry (15.3%) and TRAMI registry (20.3%). Re-hospitalization due to heart failure (22%) during the first year after MitraClip implantation was similar to TCVT registry (22.8%) and TRAMI registry (14.1%). The incidence of repeat mitral valve procedures became necessary in 8.0% of patients (9.7% in ACCESS-EU, 3.8% in TCVT, 8.5% in TRAMI registry), half of them were surgical interventions and the other half were repeated MitraClip procedures. In contrast, EVEREST II trial had 21% of repeated mitral valve procedures and all of them were surgical reinterventions. Such results show the technical experience and growing knowledge in MitraClip interventions.

No differences were made between degenerative and functional MR in this report. Chiarito and al. (18) have reported that patients with functional MR have a significantly higher functional class (NYHA functional class III or IV) and a higher rate of rehospitalization for heart failure at one year after a MitraClip implantation, meaning that functional and degenerative MR are two conditions that differ from each other and that they may have variable treatment.

New multicenter randomized controlled trials have compared transcatheter mitral-valve repair plus optimal medical therapy and optimal medical therapy alone in patients with functional MR. Published in August 2018, MITRA-FR trial (the Multicentre Study of Percutaneous Mitral Valve Repair MitraClip Device in Patients With Severe Secondary Mitral Regurgitation), involving patients with severe secondary MR and LVEF < 40%, demonstrated that despite its apparent safety and efficacy, the MitraClip does not improve patients' prognosis with no significative difference of death or unplanned hospitalization for heart failure at 1 year between groups (19). These results suggest that poor prognosis is related to underlying cardiac disease, rather than mitral insufficiency which is probably only a marker of severity of the disease. In contrast, the COAPT trial (the Cardiovascular Outcomes Assessment of the MitraClip Percutaneous Therapy), involving patients with heart failure and moderate-to-severe or severe functional MR, published in September 2018, demonstrated a lower rate of hospitalization for heart failure, lower mortality and better quality of life and functional capacity with transcatheter mitral valve repair than with medical therapy alone within 2 years of follow-up (20). Different results between the two trials likely relate to patient selection, medication changes during the trial, level of operator experience and the outcomes achieved, as well as duration of follow-up. RESHAPE-HF (A Randomized Study of the MitraClip Device in Heart Failure Patients with Clinically Significant Functional Mitral Regurgitation), a similar trial, must add some clarity to explain the very different results between MITRA-FR and COAPT trials.

Study limitations

First, this study was limited because data collection was retrospective. A large amount of follow-up data on functional status or echocardiographic outcomes were missing at the time of the database creation. For example, functional capacity at the time of discharge from the hospital was not often reported. Therefore, results are subject to selection bias. Second, this is a relatively small patient population. Third, a proportion of patients was not yet eligible for the 2-year follow-up at the time of the data analysis.

CONCLUSIONS

The MitraClip procedure in the University Hospital of Lausanne for patients with MR and at high surgical risk appeared to be a safe and effective alternative facilitating the reduction of mitral regurgitation and improving functional capacity. Primary and secondary outcomes are similar to those observed in other

registries. To complete and confirm results obtained further studies have to demonstrate the improvement of MR, functional status at 1-year or more after the procedure in our institution.

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