Mitraclip therapy and surgical mitral repair in patients with moderate to severe left ventricular failure causing functional mitral regurgitation: a single-centre experience†

Maurizio Taramasso¹, Paolo Denti², Nicola Buzzatti³, Michele De Bonis⁴, Giovanni La Canna⁴,
Antonio Colombo⁵, Ottavio Alfieri¹ and Francesco Maisano⁶,⁷

Abstract

OBJECTIVES: Surgical mitral repair is the conventional treatment for severe symptomatic functional mitral regurgitation (FMR). Mitraclip therapy is an emerging option for selected high-risk patients with FMR. The aim of this study was to report the outcomes of patients who underwent a surgical mitral repair and Mitraclip therapy for FMR in our experience.

METHODS: From March 2000 and April 2011, 143 patients with FMR were treated in our institution: 91 patients (63.6%) underwent surgical mitral repair (49% ischaemic; 51% idiopathic) and 52 (36.4%) underwent Mitraclip implantation (71% ischaemic; 29% idiopathic). Associated procedures in the surgical group were myocardial revascularization in 35%, tricuspid repair in 25% and atrial fibrillation ablation in 26%. Follow-up was 100% complete (median 18; 6.4–45 months for surgery and 8.5; 4–12 months for Mitraclip).

RESULTS: Mitraclip patients were older (P = 0.04), had higher log EuroSCORE (P < 0.0001), lower LVEF (P = 0.006) and higher left ventricular diameter (P = 0.01 for left ventricular end-diastolic diameter and P = 0.05 for left ventricular end-systolic diameter). Major post-operative infection or sepsis occurrence was higher in the surgical group (16.3 vs. 3.8%; P = 0.01), while no differences were observed in terms of acute renal failure, cardiogenic shock, cerebrovascular accident and acute myocardial infarction. Length-of-stay was 11 days (IQR: 7–19 days) for surgery and 5 days (IQR: 4–9 days) for MitraClip (P < 0.0001). In-hospital mortality was 6.6% for surgery (6/91) and 0% for Mitraclip (P = 0.01). Surgery was identified as a predictor of in-hospital death (OR: 2.61; P = 0.01). Residual MR ≥ 3+ at discharge was 0% for surgery and 9.6% for MitraClip (P = 0.002). At follow-up, actuarial survival at 1 year was 88.9 ± 3.5% for surgery and 87.5 ± 7% for Mitraclip (P = 0.6). Actuarial freedom from MR ≥ 3+ at 1 year was 79.1 ± 8% for MitraClip and 94 ± 2% for surgery (P = 0.01). At last follow-up, most of the survivors were in NYHA class I–II.

CONCLUSIONS: Mitraclip therapy is a safe therapeutic option in selected high-risk patients with FMR, and it is associated with a lower hospital mortality and shorter length-of-stay compared with surgery, in spite of worse preoperative conditions. Early and 1-year rates of recurrent MR are higher with Mitraclip. Further studies are needed to determine the long-term clinical impact.

Keywords: Mitral regurgitation • Percutaneous mitral repair • Functional mitral regurgitation • MitraClip

INTRODUCTION

Functional mitral regurgitation (FMR) is a frequent complication in heart failure patients with post-ischaemic or idiopathic dilated cardiomyopathy due to left ventricular (LV) dysfunction and remodelling [1]. Surgical repair of severe FMR in this setting has been demonstrated to improve symptoms and quality of life leading to reverse LV remodelling in a significant proportion of the patients [2–4]. Undersized mitral annuloplasty represents the standard practice in the surgical treatment of FMR [2]. However, perioperative mortality after mitral surgery for FMR is not negligible [5]. Moreover, a large number of patients with FMR are not referred for surgery, and many other patients are rejected for open heart surgery because of a predicted high surgical risk or co-morbidities [6]. Thus, new percutaneous techniques have been recently developed to treat MR with less-invasive approaches. The MitraClip system (Abbott Vascular, Menlo Park, CA, USA) is a percutaneous edge-to-edge procedure that mimics the surgical procedure [7]. Percutaneous mitral repair with the MitraClip device has been used to treat both functional and degenerative MR [8–10].

The aim of the present study was to report the in-hospital and mid-term outcomes of surgical mitral repair and MitraClip therapy to treat symptomatic patients with severe FMR and...
was waived in view of its observational and anonymous nature. The need for consent to participate in this research study and all patients gave informed written consent for the procedure performed in accordance with the institutional ethics committee, data were collected prospectively. The study protocol was performed in accordance with the institutional ethics committee, and all patients gave informed written consent for the procedures. The need for consent to participate in this research study was waived in view of its observational and anonymous nature.

**METHODS**

We retrospectively analysed the clinical and echocardiographic data of a cohort of selected patients who underwent surgical mitral repair with undersized annuloplasty with or without coronary artery bypass grafting between 2001 and 2011 and all the patients who underwent MitraClip therapy between 2008 and 2011 for severe (4+/4+, vena contracta ≥7 mm) or moderately severe (3+/4+, vena contracta = 5.5–6.9 mm) symptomatic and refractory to medical therapy FMR, for ischaemic or idiopathic dilated cardiomyopathy. Selection criteria for the surgical patients were: only the patients with 100% complete clinical and echocardiographic baseline and follow-up data were included in order to make matched comparisons with the MitraClip group; only the patients who had mitral repair with an isolated undersized annuloplasty were included; patients with a concomitant mitral repair technique associated with undersized annuloplasty were excluded. All the patients of the MitraClip group had 100% complete clinical and echocardiographic baseline and follow-up data. All the patients underwent preoperative coronary angiogram and transesophageal Doppler echocardiography (TEE). Clinical, Doppler echocardiographic, operative, and outcome data were collected prospectively. The study protocol was performed in accordance with the institutional ethics committee, and all patients gave informed written consent for the procedures. The need for consent to participate in this research study was waived in view of its observational and anonymous nature.

**Surgical mitral repair**

All patients underwent surgery through a midline sternotomy and hypothermic cardiopulmonary bypass. The mitral valve (MV) was approached through a conventional left atriotomy. All patients received an undersized annuloplasty with a complete ring, rigid or semirigid (Seguin; St Jude Medical, Inc., MN, USA; Carpentier-Edwards Physio–Edwards Lifesciences, CA, USA; Geoform–Edwards Lifesciences, CA, USA). As a general rule, the implanted ring was about two sizes smaller than the measured intertrigonal distance of the MV. An intra-aortic balloon pump (IABP) was prophylactically inserted in patients with extremely severe LV dysfunction through the right femoral artery. We used this approach both in ischaemic and non-ischaemic patients in order to decrease the afterload in the early phase of the post-mitral repair.

**Percutaneous edge-to-edge repair with MitraClip implantation**

The procedure was performed under general anaesthesia in a hybrid operating room, under TEE and fluoroscopic guidance. Live real-time 3D echocardiography was used to improve the conduct of the implantation. Transeptal puncture was performed using a Brockenbrough needle through peripheral venous access at the right groin. A steerable guide catheter was advanced into the left atrium through the transeptal puncture. The delivery system was inserted and the MitraClip device was implanted in correspondence with the origin of the regurgitation jet, perpendicularly to the coaptation line. If the effect of the implant was satisfactory, the clip was deployed. When necessary, more than 1 clip was implanted. The comprehensive description of the procedure is reported elsewhere [11].

**Patient selection**

Patients were selected if they met basic criteria for intervention from the European Society of Cardiology Task Force recommendation on the management of valvular heart disease [12]. All the patients underwent transthoracic echocardiography (TTE) followed by TEE examination at baseline. The severity of FMR was graded as: mild, 1+ (jet area/left atrial area <10%); moderate, 2+ (jet area/left atrial area 10–20%); moderately severe, 3+ (jet area/left atrial area 20–45%) and severe, 4+ (jet area/left atrial area ≥45%). The vena contracta width at the narrowest portion of the regurgitant jet and the site of origin of the jet were also assessed. Other echocardiographic measurements included LV end-diastolic area (LVEDA) and end-systolic diameter (LVESD), LVEF calculated with the Simpson method, MV tenting area and coaptation depth in mid-systole at the area of the regurgitant jet. In case of severe LV dysfunction, dobutamine stress echocardiography was performed to assess the presence of a contractile reserve. This information was useful to better define the surgical risk and, in patients who were ischaemic DCM candidates for surgery, to distinguish those who could benefit from concomitant myocardial revascularization.

In the last years, since the MitraClip program was started in our institution, the individual selection of treatment (surgery vs. MitraClip) was based on a multimodality decision-making process including the evaluation of surgical risk by logistic EuroSCORE (http://www.euroscore.org/) as well as adjunctive risk evaluation such as the presence of advanced liver cirrhosis, severe neurological impairment and frailty.

Preoperative echocardiography played a critical role in patient selection for MitraClip implantation, according to the EVEREST criteria for FMR (central MR with a basal area >4 cm², coaptation length of at least 2 mm, coaptation depth <11 mm) [8]. However, several patients with criteria beyond EVEREST recommendations were treated.

**Follow-up**

All the patients were followed up after discharge in a dedicated outpatient clinic with physical examination, ECG, TTE and arrhythmology consultation whenever indicated. The first follow-up was performed ~3 months after the surgery and then every 6 months. Follow-up was 100% complete.

**Statistical analysis**

Statistical analysis was conducted using the JMP 8.0 software (SAS Institute, Inc., NC, USA). Continuous variables are presented as mean ± SD or as median (IQR: Q1–Q3) and categorical variables are expressed as percentages. Univariable comparisons were performed with Student’s unpaired or paired t-test for continuous normally distributed data, which was tested by the
RESULTS

Patient characteristics

A total of 143 patients with severe FMR were treated between 2001 and 2011: 91 patients (63.3%) underwent surgical mitral repair (49% ischaemic aetiology; 51% idiopathic dilated cardiomyopathy) and 52 (36.4%) underwent Mitraclip implantation (71% ischaemic aetiology; 29% idiopathic dilated cardiomyopathy). Associated procedures in the surgical group were myocardial revascularization in 35%, tricuspid repair in 25% and atrial fibrillation ablation in 26%; isolated mitral repairs without associated procedures were performed in 32/91 patients (35% of the surgical patients). One patient of the MitraClip group had PTCA the day before the MitraClip implantation.

Patients who underwent MitraClip implantation patients were older ($P = 0.04$) and had a higher predicted surgical risk with log EuroSCORE ($P < 0.0001$). The prevalence of chronic renal failure, NYHA functional class, and the Chi-square test for categorical data. Survival and freedom from death were performed with nominal logistic regression.

Procedural and in-hospital outcomes

In-hospital mortality was 6.6% in the surgical group (6/91 patients: 2 patients died from acute cardiogenic shock, 3 from multiorgan failure secondary to Gram negative sepsis, 1 after emergent MV replacement due to endocarditis). No in-hospital deaths occurred in patients treated by MitraClip ($P = 0.01$).

The procedural success of the MitraClip procedure was 98.1%: one patient was converted to conventional surgical MV replacement because of a posterior leaflet laceration. One clip was implanted in 11 patients, two clips were implanted in 38 and three clips were implanted in 3.

Prophylactic support with IABP was used in 46 patients (50.5%) in the surgical group and in 1 (1.9%) in the MitraClip group ($P < 0.0001$); IABP support was required during the postoperative course in the adjudicate 14 patients (15.4%) in the surgical group and in 6 (11.5%) in the MitraClip group ($P = 0.5$).

The incidence of postoperative major infection or sepsis was higher in the surgical group (16.3 vs. 3.8%; $P = 0.01$). Three patients of the surgical group and the patient of the MitraClip group who had conversion to surgery underwent surgical revision for mediastinitis.

No differences were observed in terms of acute renal failure, need for high-dose inotropic support, cerebrovascular accident and acute myocardial infarction between the two groups.

Postoperative median length-of-stay (LOS) was 11 days (IQR: 7–19 days) for surgery and 5 days (IQR: 4–9 days) for MitraClip ($P = 0.0001$).

Predischarge echocardiography showed a residual MR ≥3+ in 0 patients of the surgical group and in 5/52 patients (9.6%) for MitraClip ($P = 0.002$). Figure 1 shows the predischarge MR grade in the two groups.

<table>
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<tr>
<th>Table 1: Preoperative clinical features</th>
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<tr>
<td><strong>Surgery</strong> ($n = 91$)</td>
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<tr>
<td>Age (years)</td>
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<tr>
<td>Female gender, n (%)</td>
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<tr>
<td>Previous AMI, n (%)</td>
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<tr>
<td>Log EuroSCORE, n (%)</td>
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<tr>
<td>Previous cardiac surgery, n (%)</td>
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<tr>
<td>Coronary artery disease, n (%)</td>
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<tr>
<td>Atrial fibrillation, n (%)</td>
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<td>Chronic renal failure, n (%)</td>
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<td>COPD, n (%)</td>
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<td>Cerebrovascular disease, n (%)</td>
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<td>Diabetes, n (%)</td>
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<td>NYHA functional class, n (%)</td>
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<td>I</td>
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<td>III</td>
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AMR: acute myocartrial infarction; COPD: chronic obstructive pulmonary disease; NYHA: New York Heart Association. *Student’s unpaired t-test for continuous data; Chi-square test for categorical data.

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<th>Table 2: Preoperative echocardiography</th>
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<tr>
<td><strong>Surgery</strong> ($n = 91$)</td>
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<tr>
<td>LV ejection fraction (%)</td>
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<tr>
<td>LVEDD (mm)</td>
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<tr>
<td>LVESD (mm)</td>
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<tr>
<td>sPAP (mmHg)</td>
</tr>
<tr>
<td>TR 3–4+, n (%)</td>
</tr>
<tr>
<td>Tenting area (cm²)</td>
</tr>
<tr>
<td>Coaptation depth (cm)</td>
</tr>
<tr>
<td>Septolateral mitral diameter (mm)</td>
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<tr>
<td>Intercommissural mitral diameter (mm)</td>
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LV: left ventricle; LVEDD: left ventricle end-diastolic diameter; LVESD: left ventricle end-systolic diameter; sPAP: systolic pulmonary artery pressure; TR: tricuspid regurgitation. *Student’s unpaired t-test for continuous data; Chi-square test for categorical data.
The majority of the patients who underwent MitraClip implantation were discharged home (32/52 patients, 61.2% of the total), while all surgical patients were transferred to a cardio-pulmonary rehabilitation facility. Table 3 summarizes the peri-procedural results.

Surgery was identified as the only individual predictor of in-hospital death at logistic analysis (OR: 2.61; \( P = 0.01 \)), independently from preoperative status, comorbidities, LV function and dimensions.

Follow-up

Follow-up was 100% complete (median 18; 6.4–45 months for surgery and 8.5; 4–12 months for Mitraclip).

Cumulative cardiovascular death was 9.9% in the surgical group (9/91 patients: 2 patients died from ischaemic stroke, 2 from bacterial endocarditis, 2 from acute cardiacogenic shock and 3 from multiorgan failure secondary to Gram negative sepsis) and 3.8% in the MitraClip group (2/52 patients: 1 patient with residual moderate to severe MR died from refractory heart failure and 1 from acute pulmonary oedema and superimposed pulmonary infection) \( P = 0.2 \).

CVVH: continuous veno-venous haemofiltration; LCOS: low cardiac output syndrome; AMI: acute myocardial infarction; MR: mitral regurgitation.

*Chi-square test.

Table 3: Perioperative results

<table>
<thead>
<tr>
<th></th>
<th>Surgery (( n = 91 ))</th>
<th>MitraClip (( n = 52 ))</th>
<th>P-value*</th>
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<tbody>
<tr>
<td>In-hospital mortality, ( n ) (%)</td>
<td>6 (6.6)</td>
<td>0</td>
<td>0.01</td>
</tr>
<tr>
<td>Acute kidney injury, ( n ) (%)</td>
<td>28 (30.7)</td>
<td>16 (30.7)</td>
<td>1</td>
</tr>
<tr>
<td>Need for CVVH, ( n ) (%)</td>
<td>2 (2.2)</td>
<td>3 (5.8)</td>
<td>0.2</td>
</tr>
<tr>
<td>LCOS, ( n ) (%)</td>
<td>3 (3.3)</td>
<td>4 (7.7)</td>
<td>0.2</td>
</tr>
<tr>
<td>Major infection/sepsis, ( n ) (%)</td>
<td>15 (16.5)</td>
<td>3 (5.8)</td>
<td>0.02</td>
</tr>
<tr>
<td>Stroke, ( n ) (%)</td>
<td>2 (2.2)</td>
<td>0</td>
<td>0.2</td>
</tr>
<tr>
<td>AMI, ( n ) (%)</td>
<td>0</td>
<td>0</td>
<td>Na</td>
</tr>
<tr>
<td>Discharge MR ≥ 3+, ( n ) (%)</td>
<td>0</td>
<td>5 (9.6)</td>
<td>0.002</td>
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Figure 1: Predischarge mitral regurgitation in each group.

Figure 2: Mitral regurgitation grade at 1-year follow-up (comparison made by log-rank method).

Figure 3: Actuarial survival at follow-up (comparison made by log-rank method).

Actuarial freedom from MR ≥ 3+ at 1 year was 79.1 ± 8% for MitraClip and 94 ± 2% for surgery \( P = 0.01 \) (Fig. 2).

Actuarial survival at 1 year was 88.9 ± 3.5% for surgery and 87.5 ± 7% for Mitraclip \( P = 0.6 \) (Fig. 3). In both groups, an improvement in LVEF was documented [from 32.1 ± 8.6 to 38.6 ± 11.3% for surgery \( P < 0.0001 \) and from 27.7 ± 10 to 35.3 ± 10.8% for MitraClip \( P = 0.0002 \)]).

Reduction in LV dimensions was observed in both groups: LVEDD decreased from 66.4 ± 8.5 to 58.5 ± 10.1 mm in patients who underwent surgery \( P < 0.0001 \) and from 70.2 ± 7.7 to 65.4 ± 8.3 mm in patients who underwent MitraClip implantation \( P = 0.005 \). A decrease in sPAP was present in both groups (from 43.9 ± 12.4 to 37.7 ± 10.7 mmHg for surgery and from 46.9 ± 15.4 to 41.7 ± 15.9 mmHg for MitraClip, \( P = 0.006 \) and \( P = 0.007 \), respectively).

At 1-year follow-up, 88.7% of the patients of the surgical group and 84.1% of the patients of the MitraClip group were in NYHA functional class I–II \( P = 0.6 \). In the MitraClip group, 47.7% of the patients were asymptomatic (NYHA class I), compared with 22% of the patients of the surgical group \( P = 0.006 \) (Fig. 4).

Long-term follow-up was available only for the patients who underwent surgery (29.7 ± 28 months); the latest echocardiography showed an LVEF of 37.8 ± 10.9% and an LVEDD of 59.1 ± 9.6 mm. No cases of mitral stenosis were observed. Freedom
Incidence of late reoperation compared with patients who have absence of concomitant annuloplasty is associated with a higher approach was provided by Maisano et al. [15]. Surgical correction of FMR is controversial, because FMR is functional MR is associated with a poor prognosis in heart failure patients with post-ischaemic or idiopathic dilated cardiomyopathy [13, 14]. In severely symptomatic patients with severe FMR despite optimal medical therapy and cardiac resynchronization therapy, surgical mitral annuloplasty may be considered [15]. Surgical correction of FMR is controversial, because FMR is the consequence, and not the cause, of an LV dysfunction. Prospective randomized trials to determine whether surgical correction of FMR improves mortality and heart failure in this mainly ventricular disease have never been conducted. The most important benefits of surgical treatment are improvements in symptoms and quality of life, which have been reported in several studies [16]. Moreover, after the surgical treatment of FMR LV reverse remodelling has been observed in a substantial proportion of patients [4].

Operative mortality after mitral surgery for FMR is not negligible, ranging from 8.8 to 21% [17-20], and the number of patients with severe FMR who are not referred for surgery because of high surgical risk, advanced age and comorbidities is increasing [6].

Surgical experience suggests that edge-to-edge repair in the absence of concomitant annuloplasty is associated with a higher incidence of late reoperation compared with patients who have annuloplasty [7, 21]. The clinical proof for a ringless endovascular approach was provided by Maisano et al. [22] who reported mid-term results comparable to conventional repair techniques with annuloplasty with isolated edge-to-edge repair in well-selected patients with preserved annular function.

The safety and the efficacy of the percutaneous edge-to-edge with the MitraClip have been initially tested in the EVEREST I trial [8] and then compared with surgery in the randomized EVEREST II trial. The results of the randomized EVEREST II trial showed that in carefully selected patients, the MitraClip treatment is superior in safety, with an acceptable margin of decreased efficacy in reducing MR compared with surgery [9]. However, most of the patients enrolled in the EVEREST trial had degenerative MR.

On the basis of the good results that have been reported with the surgical treatment of FMR with the edge-to-edge technique [23], the percutaneous edge-to-edge technique with MitraClip implantation has been used for FMR in high-risk end-stage patients with results showing it to be safe and efficacious [10, 24, 25].

The preliminary results of the ACCESS registry, an ongoing observational post-marketing registry in which >70% of the patients treated with MitraClip were high-risk surgical candidates with FMR, showed the excellent efficacy and safety of the procedure, with almost all patients experiencing MR reduction with a hospital mortality of ~2% (Maisano F. Data from the European ACCESS registry: what patients have been treated in Europe. Transcatheter Cardiovascular Therapeutics (TCT) Meeting, 21–25 Sep 2010, Washington, DC).

In the present study, the single-centre experience with the percutaneous treatment of FMR in selected high-risk patients was retrospectively compared with a surgical series of patients who underwent undersized mitral annuloplasty.

DISCUSSION

Functional MR is associated with a poor prognosis in heart failure patients with post-ischaemic or idiopathic dilated cardiomyopathy [13, 14]. In severely symptomatic patients with severe FMR despite optimal medical therapy and cardiac resynchronization therapy, surgical mitral annuloplasty may be considered [15]. Surgical correction of FMR is controversial, because FMR is the consequence, and not the cause, of an LV dysfunction. Prospective randomized trials to determine whether surgical correction of FMR improves mortality and heart failure in this mainly ventricular disease have never been conducted. The most important benefits of surgical treatment are improvements in symptoms and quality of life, which have been reported in several studies [16]. Moreover, after the surgical treatment of FMR LV reverse remodelling has been observed in a substantial proportion of patients [4].

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Safety

The results of the present study confirm the safety of MitraClip therapy in the setting of FMR, even in the presence of an extremely high surgical risk. Patients who underwent MitraClip therapy had lower EF, more advanced ventricular remodelling and more dilated mitral annulus, reflecting a more advanced phase of the disease. Moreover, patients who underwent MitraClip implantation had a log EuroSCORE >2-fold higher than patients of the surgical group and the copathologies burden was heavier in the MitraClip patients (CRF, diabetes, pulmonary disease, concomitant coronary artery disease).

In spite of a much worse risk profile at baseline, the MitraClip was associated with a lower hospital mortality than surgery (0 vs. 6.6%; P = 0.01), shorter postoperative LOS (11 days for surgery and 5 days for MitraClip; P < 0.0001) and reduced major infections occurrence (3.8% vs. 16.5%; P = 0.02). Moreover, the majority of the patients who underwent MitraClip implantation had a fast recovery and were discharged home.

These results point out the concept that in end-stage patients who are not amenable for surgery a less-invasive approach, like MitraClip therapy, should be considered, in order to improve clinical outcomes. Despite good results having been reported also in the presence of an adverse valve morphology [25], the anatomical eligibility of the patients remains an open issue.

On the other hand, in-hospital mortality in the surgical group was acceptable and congruent with other surgical series [17-20], confirming that appropriate patient selection is the key to achieving good results.

Despite the higher rate of MR recurrence and the potential advantages of the associated surgical procedures (atrial fibrillation ablation, tricuspid repair and myocardial revascularization), it is interesting to point out that actuarial survival at 1 year was similar between the two groups and that an improvement in functional status was achieved in all the patients with the majority of the patients in NYHA functional class I-II at 1-year follow-up, of whom 47.7% in the MitraClip group and 22% in the surgical group were asymptomatic.

Figure 4: NYHA functional class at 1-year follow-up.
Efficacy

Residual MR after surgical repair is associated with poor survival. Crabtree et al. reported an actuarial survival of 76.4% at 3 years and 65.1% at 5 years after surgery in patients with 0 to 2+ MR postoperatively vs. 61.3 and 35.8% in patients with 3+- MR ($P = 0.003$) [25]. Moreover, in a surgical series of 111 patients De Bonis et al. [4] reported that the progression of LV remodelling paralleled the recurrence of MR after repair and it was associated with poor outcome.

In our experience, all the patients who underwent MitraClip therapy had an acute reduction in MR grade after the procedure: MR grades of 2+ or less were acutely achieved in 96% of the patients. This result is significantly higher than the 74 and 76% reported in EVEREST I and EVEREST II trials, respectively, in which the majority of the patients had degenerative MR [8, 9], suggesting that MitraClip therapy could be more effective in the treatment of FMR. Moreover, it has been observed in our experience that often >1 clip has to be used (78.8% of the cases) in order to obtain an acceptable reduction of the regurgitant jet.

When compared with the surgical group, incidence of residual MR at discharge was higher in patients who underwent MitraClip therapy (9.6% of the patients in the MitraClip group had MR ≥3+, compared with 0% of the patients in the surgery group – $P = 0.002$).

At 1 year, freedom from MR ≥3+ was significantly lower in patients who underwent surgery compared with the MitraClip treatment, confirming the higher efficacy of surgery in FMR. Despite the higher MR degree in the MitraClip group, improvement in LV systolic function and a certain degree of LV reverse remodelling were documented in both groups at follow-up.

In conclusion, this study shows that MitraClip therapy in selected high-risk patients with FMR is a safe procedure and can improve, in LV systolic function and a certain degree of LV reverse remodelling documented in both groups at follow-up.

Randomised selected groups would be required in a prospective study in order to compare the different treatments and to eliminate selection bias and to make direct comparisons of the results.

LIMITATIONS

This study was an observational, retrospective single-centre study; therefore the size was too small to make firm conclusions. The groups were not randomized into the different treatment arms, and results include the initial learning curve. Moreover, the two groups of this study were not numerically homogeneous. Randomised selected groups would be required in a prospective study in order to compare the different treatments and to eliminate selection bias and to make direct comparisons of the results.

Another important limitation is that the follow-up of the patients of the MitraClip group was shorter than the follow-up period of the surgical group. Moreover, the selection bias was accentuated because the two treatments were available at the same time only for the last 3 years (MitraClip program started in 2008 in our institution).

ACKNOWLEDGEMENT

We are grateful to Andrea Guidotti and Micaela Cioni for their precious support.

Conflicts of interest: Francesco Maisano is consultant for Abbott Vascular; Ottavio Alfieri has a financial relationship with Edwards Lifesciences.

REFERENCES

Dr B. Mochtar (Maastricht, Netherlands): Your Milano team has shown promising results with the MitraClip procedure in selected patients; as a benchmark, you use your surgical group to compare the results. But I have two questions. First, about the methodology you used in your study groups: what were the effects, the real definition of functional mitral regurgitation in both groups, because you used the EVEREST criteria, as far as I can see, only for the MitraClip procedure?

Dr Taramasso: This is, of course, a limitation of our study. We used EVEREST criteria only for the MitraClip patients, but we also treated a lot of the patients beyond these criteria which may also in part explain our results. We used these criteria only in patients who were not amenable for surgery and who have been evaluated by our heart team since 2008, which was the date when we started the MitraClip programme in our institution.

Dr Mochtar: The surgery group was a historical control group; they had a preoperative worse condition of the patients treated with MitraClip were at very high risk for surgery. This paper shows that even a high-risk patient for surgery can be treated with satisfactory peri-procedural results because the procedural mortality is zero in MitraClip patients. So this is really the measure of the paper. You are right in many aspects. There are two different categories of patients. But really, the purpose of the paper is to show that in severe heart failure, the MitraClip can be a solution.

Dr R. Klautz (Leiden, Netherlands): May I make one remark: Beauty is always in the eye of the beholder. And if you look at the data the way you look at it, it looks like a very promising result. But if you look at it in the more longer term, you see that obviously the nonsurgical group has a better in-hospital outcome than the surgical group, but the attrition rate at one year is much more in the MitraClip procedure. So at one year the mortality in the MitraClip group is already compensating for the surgical mortality in the surgical group. So what do you expect is going to happen in 2 or 3 years?

Dr Taramasso: We will see. It’s a good point. But one-year mortality between the two groups was similar. The preoperative worse condition of patients with 1.5, 1.6, 1.4 coaptation depths. That explains the difference between the different publications.