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Impact and evolution of right ventricular dysfunction after successful MitraClip implantation in patients with functional mitral regurgitation

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ABSTRACT

Background: Right ventricular dysfunction (RVdysf) is a predictor of poor outcome in patients with heart failure and valvular disease. The aim of this study was to evaluate the evolution and the impact of RVdysf in patients with moderate–severe functional mitral regurgitation (FMR) successfully treated with MitraClip.
Methods and results: From October 2008 to July 2014, 60 consecutive high surgical risk FMR patients were evaluated and stratified into two groups: RVdysf group (TAPSE < 16 mm and/or S′TDI <10 cm/s, 21 patients) and No-RVdysf group (38 patients). The overall mean age of patients was 73 ± 8 (83% male). Ischemic FMR etiology was present in 67%. Mean LVEF was 30 ± 10%. Overall mean time follow-up was 565 ± 310 days. The only significant difference between the two groups was a greater prevalence of stroke, ICD and use of aldosterone antagonist in RVdysf group. Acute procedural success was achieved in 90% of patients. At 6-month echo-matched analysis significant RV function improvement was observed in patients with baseline RVdysf (TAPSE 15 ± 3.0 vs. 19 ± 4.5, p = 0.007; S′TDI 7 ± 1.2 vs. 11 ± 2.8, p < 0.0001; baseline vs. 6-month, respectively). The mean improvement in the 6-min walking test was significant in both groups (120 and 143 m, RVdysf and No-RVdysf groups, respectively). At Kaplan–Meier analysis, the presence of RVdysf did not affect the outcome in terms of freedom from composite efficacy endpoint.
Conclusions: This study shows that successful MitraClip implantation in patients with FMR and concomitant right ventricular dysfunction yields significant improvement of RV function at mid-term follow-up. Further data on larger population will be required to confirm our observations.

1. Introduction

Mitral regurgitation (MR) represents the second most common valvular disease in Europe [1]. This pathology evolves over many years, allowing the heart to adapt to a chronic volume overload, leading to significant and complex hemodynamic and structural changes. In chronic severe MR, left ventricular remodeling leads to the development of significant pulmonary hypertension in almost half of the patients [2,3]. The increase in right ventricular (RV) afterload at first induces right atrial and RV remodeling, and afterwards leads to RV dysfunction. RV dysfunction represents a strong and independent predictor of mortality in left ventricular ischemic and non-ischemic heart failure (HF) [4–10]. Alternate effects of surgical mitral valve repair or replacement on preexisting RV dysfunction have been reported in different published series of patients [11–18] Percutaneous mitral valve repair with MitraClip has been shown to be associated with a favorable clinical outcome and left and right ventricular reverse remodeling in high-risk patients with severe MR [19–22]. In the present study we evaluated the impact and the evolution of pre-existing RV dysfunction in high-risk functional MR (FMR) patients after successful MitraClip implantation.

2. Methods

2.1. Study population and clinical endpoints

From October 2008 to July 2014, 60 consecutive MitraClip treated patients were evaluated at San Raffaele Hospital and at EMO-GVM Centro Cuore Columbus, Milan, Italy. The MitraClip procedure was considered in patients with symptomatic severe FMR who fulfilled the echocardiographic criteria of eligibility and judged inoperable or at high surgical risk by a 'heart team', and had a life expectancy greater than 1 year (according to the ESC/EACTS 2012 recommendation class

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IIb, level of evidence C). Each patient was informed regarding the possible risk and procedural benefit of MitraClip procedure and written consent was obtained for the procedure, data collection, and subsequent analysis and publication. The study was approved by the Hospital Ethics

Table 1
Preoperative clinical characteristics of patients with FMR stratified for RV dysfunction (RVdysf).

	FMR patients (n = 60)	No-RVdysf group (n = 38)	RVdysf group (n = 22)	p value
Clinical characteristics (%)				
Age, years	73 ± 8	73.6 ± 7	72 ± 8	0.478
Proportion aged >80 years	9 (15)	7 (18)	2 (9)	0.329
Male gender	50 (83)	31 (82)	19 (86)	0.632
BMI, kg/m^2	25 ± 3.6	25 ± 2.8	24 ± 4	0.651
BSA, m^2	1.8 ± 0.19	1.8 ± 0.18	1.8 ± 0.21	0.655
Hypertension	43 (72)	29 (76)	14 (64)	0.294
Hypercholesterolemia	32 (53)	21 (55)	11 (50)	0.662
Previous/Current smoker	27 (45)	16 (42)	11 (50)	0.554
Diabetes mellitus (DM)	18 (30)	10 (26)	8 (36)	0.413
Insulin-dependent DM	10 (17)	5 (13)	5 (23)	0.338
Moderate/Severe COPD	19 (32)	11 (29)	8 (36)	0.647
CRF*	36 (60)	21 (55)	15 (68)	0.325
Atrial fibrillation	21 (35)	11 (29)	11 (50)	0.103
Logistic EuroSCORE	27.2 ± 20.5	23.8 ± 18	33 ± 23	0.101
Logistic EuroSCORE >25	30 (50)	16 (42)	14 (64)	0.089
STS score mortality	7.9 ± 8.5	8.0 ± 8.7	7.7 ± 8.4	0.883
Advanced congestive HF	21 (35)	10 (26)	11 (50)	0.093
§6-MWT, m	293 ± 97	290 ± 92	298 ± 112	0.815
Ischemic FMR etiology	40 (67)	24 (63)	16 (73)	0.449
NYHA functional class (III-IV)	42 (70)	27 (71)	15 (68)	0.815
Pulmonary hypertension**	11 (18)	7 (18)	4 (18)	0.916
Coronary artery disease	42 (70)	24 (63)	16 (73)	0.115
Three-vessel disease	22 (37)	14 (37)	8 (36)	0.970
Chronic stable angina	9 (15)	5 (13)	4 (18)	0.606
Previous pulmonary edema	28 (47)	16 (42)	12 (54)	0.355
Previous AMI	38 (63)	21 (55)	17 (77)	0.119
Previous PCI	31 (52)	18 (47)	13 (59)	0.384
Previous CABG	17 (28)	10 (26)	7 (32)	0.658
Peripheral vascular disease	13 (22)	6 (16)	7 (32)	0.146
Previous stroke	3 (5)	0 (0)	3 (14)	**0.020**
Laboratory analysis				
NT-pro-BNP, pg/ml	9004 ± 15958	8323 ± 16258	10206 ± 15833	0.702
NT-pro-BNP ≥10.000 pg/ml	10 (17)	4 (10)	6 (27)	0.077
Sodium, mEq/l	138 ± 4	138 ± 4	138 ± 4	0.967
Hemoglobin, gr/dl	11.8 ± 1.8	11.9 ± 1.7	11.7 ± 1.8	0.752
RDW >15%	37 (62)	24 (63)	13 (59)	0.755
RDW, %	16.1 ± 2.1	15.9 ± 2.0	16.3 ± 2.1	0.551
Creatinine, mg/dl	1.06 ± 0.7	1.7 ± 0.7	1.6 ± 0.6	0.600
Bilirubin, mg/dl	0.86 ± 0.5	0.78 ± 0.55	0.99 ± 0.4	0.172
AST, units/L	59 ± 224	80 ± 283	24 ± 8	0.364
ALT, units/L	49 ± 165	67 ± 208	20 ± 9	0.309
Treatment history (%)				
Cardiovascular medication				
Loop diuretic	56 (93)	34 (89)	22 (100)	0.170
Loop diuretic, mg	138 ± 111	144 ± 113	128 ± 111	0.603
Aldosterone antagonist	29 (48)	14 (37)	15 (68)	**0.024**
Aldosterone antagonist, mg	19.5 ± 16.6	14.9 ± 15.3	23.4 ± 17.1	0.180
Beta-blocker	47 (78)	31 (82)	16 (73)	0.308
CCB	3 (5)	3 (8)	0 (0)	0.170
ACE-I/ARB	31 (52)	21 (55)	10 (45)	0.213
Ivabradine	6 (10)	3 (8)	3 (14)	0.497
Digoxin	9 (15)	6 (16)	3 (14)	0.778
Cardioaspirin	39 (60)	25 (66)	14 (64)	0.708
Dual antiplatelet therapy	17 (28)	11 (29)	6 (27)	1.000
Oral anticoagulant therapy	22 (37)	12 (32)	10 (45)	0.317
Electrical therapy				
ICD	36 (60)	19 (50)	17 (77)	**0.038**
CRT-D	11 (18)	5 (13)	6 (27)	0.173
CRT-PM	10 (17)	5 (13)	5 (23)	0.234

Data are presented as absolute numbers and percentages (for categorical variables) or mean value ± SD (for continuous variables) unless otherwise specified.
Student's unpaired t-test for continuous data; Chi-square test for categorical data.
AMI = acute myocardial infarction; ACE = angiotensin converting enzyme; ARB = angiotensin II receptor blocker; AST = aspartate aminotransferase; ALT = alanine transaminase; BMI = body mass index; BSA = body surface area; CABG = coronary artery bypass grafting; CCB = Calcium channel blockers; CRT D = cardiac resynchronization therapy with defibrillator; CRT-PM = cardiac resynchronization therapy without defibrillator; COPD = chronic obstructive pulmonary disease; ICD = implantable cardioverter defibrillator; NYHA = New York Heart Association. NT-pro-BNP = N-terminal protype-brain natriuretic peptide; PCI = percutaneous coronary intervention; RDW = red cell distribution with.
Bold numbers indicate significance at p value < 0.05.
*Chronic renal failure (CRF) was defined as an estimated glomerular filtration rate (eGFR) <60 ml/min/1.73 m^2.
**Severe pulmonary hypertension was defined as a pulmonary systolic pressure ≥60 mm Hg as estimated by doppler echocardiography.
§6-MWT = six minutes walking test, available in 34 patients (60% of patients).