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Mitral Valve Repair with the Memo 3D Annuloplasty Ring in Degenerative Mitral Regurgitation

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Abstract

Background: Mitral Valve repair (MVr) is the first-choice surgical therapy for patients developing severe Degenerative Mitral Regurgitation (DMR). The aim of the present study is to report the midterm results of MVr using the Memo 3D semi-rigid annuloplasty prosthetic ring in patients referred for DMR.

Methods: Two hundred fifty-five consecutive patients referred for severe DMR and undergoing MVr in our institution between January 2015 and December 2018 were retrospectively included. All of them underwent mitral annuloplasty with the Memo 3D prosthetic ring. Preoperative characteristics, operative data, in-hospital outcomes and one-year follow-up clinical and echocardiographic findings were analyzed. The main outcome was a composite of grade ≥ 2 recurrent Mitral Regurgitation (MR) and/or mitral valve reintervention during the first postoperative year.

Results: Thirty-day rates of death, stroke, myocardial infarction and new permanent pacemaker implantation were 2.4%, 1.2%, 0.8% and 2.4%, respectively. At one-year post-repair, 99.6% of patients were in NYHA class I-II. Freedom from grade ≥ 2 recurrent MR, reintervention and the composite outcome were 96.7%, 97.3% and 94.2%, respectively. In univariate analysis, preoperative NYHA functional status (p=0.002), pulmonary hypertension (p=0.01), LVEF (p=0.04), and MR grade at discharge (p<0.0001) were significantly associated with the main composite outcome.

Conclusion: Our study suggests that MVr with the Memo 3D semi-rigid prosthetic ring achieves satisfying and sustainable MV function, resulting in markedly improved functional status at one-year follow-up in patients with severe DMR.

Keywords: Mitral valve regurgitation; Mitral valve repair; Complete semi-rigid saddle-shaped annuloplasty ring; Memo 3D ring

Abbreviations

AF: Atrial Fibrillation; AV: Aortic Valve; CABG: Coronary Artery Bypass Grafting; CPB: Cardio-Pulmonary Bypass; DMR: Degenerative Mitral Regurgitation; LV: Left Ventricular; LVEF: Left Ventricular Ejection Fraction; LVOT: Left Ventricular Outflow Tract; MA: Mitral Annulus; MV: Mitral Valve; MVr: Mitral Valve Repair; MVR: Mitral Valve Replacement; SAM: Systolic Anterior Motion; TEE: Transesophageal Echocardiography; TTE: Transthoracic Echocardiography; TV: Tricuspid Valve

Introduction

Degenerative Mitral Regurgitation (DMR) is the second most frequent valvular heart disease in the western countries [1]. Mitral Valve repair (MVr) is the gold-standard therapy for patients referred for severe DMR, especially when the results are expected to be durable [2,3]. The Mitral Valve (MV) is a complex and asymmetrical structure undergoing dynamic changes throughout the cardiac cycle. DMR is often associated with a less dynamic, more planar and dilated Mitral Annulus (MA) [4]. MV annuloplasty is pivotal in surgical MVr, aiming to restore the normal MA geometry, avoid further dilatation and maintain a good leaflet coaptation surface in order to prevent a postoperative recurrent Mitral Regurgitation (MR) impairing Left Ventricular (LV) remodeling and

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survival [5,6]. The vast array of annuloplasty devices developed over the last decades reflects that the features of the "ideal ring" remain controversial. The Memo 3D device (Livanova, London, United Kingdom) is a complete, semi-rigid and saddle-shaped prosthetic ring. By folding MA dynamics throughout the cardiac cycle, this type of ring is supposed to offer uniform annular force distribution, better leaflet coaptation geometry and finally reduced mitral leaflet stress [7-11]. The Memo 3D ring is readily available for over fifteen years and is increasingly used, nevertheless only few studies have been published to report its efficiency [12-14]. The aim of the present study is to report the midterm results of MVr using the Memo 3D semi-rigid annuloplasty ring in the treatment of DMR.

Methods

Study design and patient population

All patients referred for DMR and proposed to MVr in our heart valve center between January 2015 and December 2018 were retrospectively included in the study. Memo 3D annuloplasty prosthetic ring was the only device used in our institution during this period. The need for concomitant Tricuspid Valve (TV) or Aortic Valve (AV) surgery, Atrial Fibrillation (AF) ablation, left atrial appendage closure or Coronary Artery Bypass Grafting (CABG) was not considered as exclusion criterion. We excluded from in-hospital and one-year follow-up analysis patients who underwent MVr without prosthetic ring, first intention MV Replacement (MVR), MVr for functional MR and those operated on an emergency basis (e.g., endocarditis, acute ischemic MR). Patients were informed that their codified data would be used for the study and all of them provided written informed consent. According to the French ethic and regulatory law (public health code), retrospective studies based on the exploitation of usual care data have to be declared to the French National Commission for Informatics and Liberties (CNIL). The Toulouse University Hospital signed a commitment of compliance to the reference methodology MR-004 of the CNIL. This study was evaluated, validated and registered according to the General Data Protection Regulation (register of retrospective study of Toulouse University Hospital, number: RnIPH 2020-89).

Definitions

MR mechanism was classified according to the Carpentier's approach, based on leaflet motion. The echocardiographic findings, as well as in-hospital and one-year mortality and morbidity, were reported according to the definitions provided by the current guidelines [15,16].

Annuloplasty prosthetic ring

The Memo 3D ring (Livanova, London, United Kingdom) is a complete, semi-rigid and saddle-shaped annuloplasty ring made of a three-layer structure. The internal super-elastic alloy core is conceived to allow physiological three-dimensional annular dynamics. The intermediate oval silicone sheath allows needle penetration for suture attachment. The external Carbofilm™ coating is added to facilitate complete endothelization, to prevent inflammatory reaction and scar tissue formation. Rings are available in 8 sizes, from 24 to 38 millimeters in 2-millimeters increments [12].

Surgical procedure

All procedures were performed through conventional median sternotomy, with standard Cardiopulmonary Bypass (CPB), central cannulation, normothermia and both anterograde and retrograde cold blood cardioplegia. After aortic cross-clamping and dissection of the Sondergaard plane, the left atrium was opened and the MV exposed with a self-retaining retractor. Functional segmental analysis of the MV was then made. The restoration of the leaflet coaptation was achieved according to usual techniques as described by Carpentier, including quadrangular or triangular resection, plication of the MA and/or placement of neochordae. Repair procedure was completed with implantation of a memo 3D ring. Sizing was based on both the height of the unfurled anterior leaflet and the inter-commissural distance. All patients underwent intraoperative Transesophageal Echocardiography (TEE) before initiation and after weaning from CPB. If TEE exhibited more than trivial residual MR, CPB was re-initiated and the MV was checked upon aortic cross-clamping. If regurgitation mechanism was not clearly understood or if significant MR persisted after a second repair, MVR was performed.

Post-operative management and patient follow-up

All patients received anticoagulation therapy for three months after surgery, that was then stopped if there was no other indication. A Transthoracic Echocardiography (TTE) was performed before discharge, usually at post-operative day 5. After hospital discharge, patients were followed up by their referring cardiologist at one, six and twelve months from surgery. The main outcome was a composite of grade ≥ 2 recurrent MR and/or MV reintervention at 1 year.

Data collection and statistical analysis

Preoperative characteristics and in-hospital clinical outcomes were extracted from patients' computerized medical record (Orbis hospital information system, Agfa HealthCare, Mortsel, Belgium). One-year follow-up outcomes were extracted from follow-up clinics and echocardiographic reports retrieved by phone calls to outpatient cardiologists. Data are expressed as means ± standard deviations and percentages. After the first descriptive statistics phase and verification of the distribution of values (Kolmogorov-Smirnov Test), the studied population was separate into 2 groups according to the presence or the absence of composite outcome. Then, categorical variables were compared using Chi-square-test and continuous variables were compared using non-parametric tests (Mann Witney test). A p value <0.05 was considered as significant. All analyses were performed in XLSTAT (Addinsoft, version 2019.1.1).

Results

Baseline characteristics

From January 2015 to December 2018, 255 consecutive patients referred to our Heart Valve Center for severe DMR were allocated by the Heart Team to undergo surgical MVr (Figure 1). Mean age was 64.7 ± 12.3 years and 188 patients were men (73.7%, Table 1). One third of them (n=80) had NYHA ≥ 3/4 functional status and 100 patients had previous AF (39.2%). The prevalence of coronary artery disease, chronic obstructive pulmonary disease and chronic kidney disease were 4.7%, 8.2% and 10.2%, respectively, and the mean EuroSCORE II was 1.9 ± 1.9%. All patients had grade 3 to 4 MR (n=26, 10.2% and n=229, 89.8% respectively). According to the Carpentier's functional classification, all the patients had type II MR (at least one leaflet segment prolapse). Mean LV Ejection Fraction (LVEF) was 61.6 ± 8.5% and 108 patients had pulmonary hypertension (42.4%).

Operative data

Mean CPB and cross-clamp times were 84.4 ± 31.2 and 63.4 ± 25.1 minutes, respectively (Table 2). Half of the patients underwent

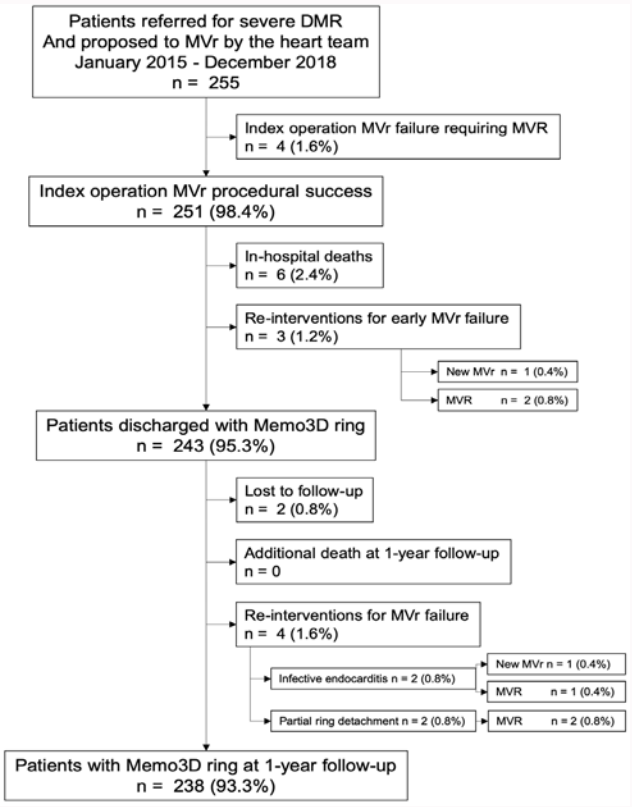

Figure 1: Patient flow though the study.
DMR: Degenerative Mitral Regurgitation, MVr: Mitral Valve repair, MVR: Mitral Valve Replacement

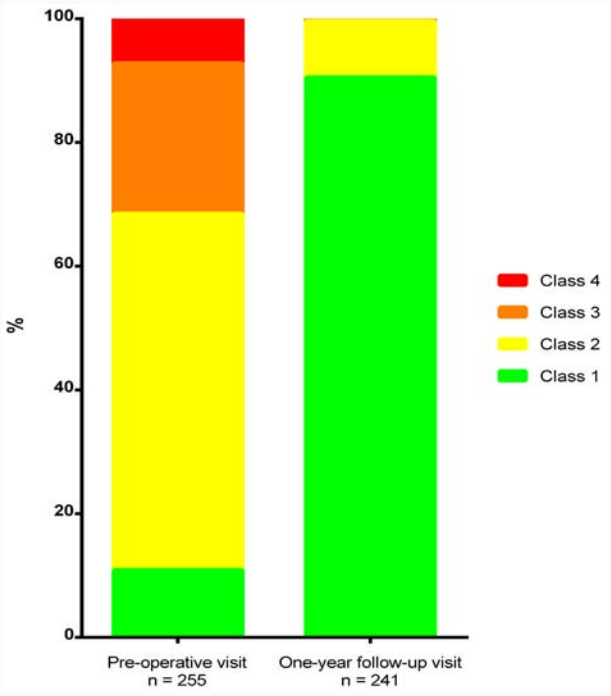

Figure 2: NYHA functional class at the preoperative and one-year follow-up visits, percentage of overall for each class.
NYHA: New York Heart Association

quadrangular leaflet resection with annulus plication (n=128), 36 triangular resection (14.1%) and 65 had at least one neo-chordae

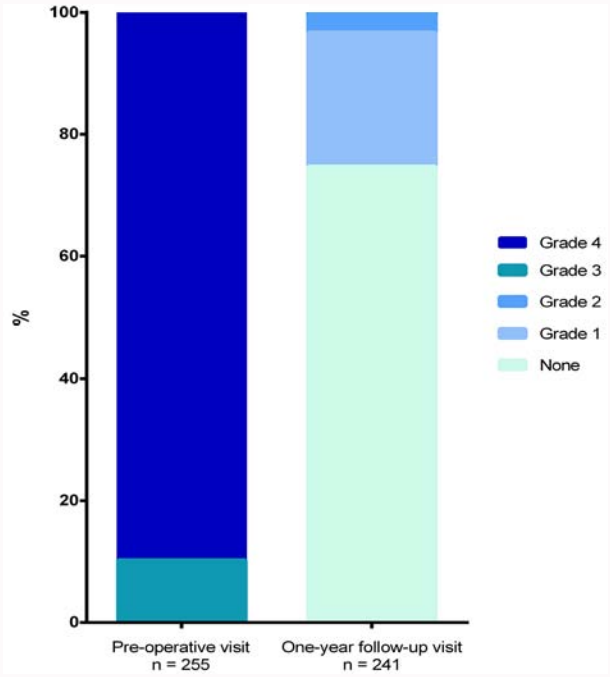

Figure 3: Mitral regurgitation severity at the preoperative and one-year follow-up visits, percentages of overall for each grade.

implantation (25.5%). The most implanted ring sizes ranged from 30 to 36 mm (n=222, 87%). Concomitant AF ablation, TV annuloplasty, AV surgery and CABG were performed in 27.1%, 22.7%, 5.1% and 11.8% of the patients, respectively. Procedural success rate was 98.4%. Repair failure requiring MVR occurred in 4 patients: Three of them had complex bileaflet prolapse and/or lesions involving the commissural areas, one had post-repair Systolic Anterior Motion (SAM) inducing LV Outflow Tract (LVOT) obstruction and severe recurrent MR.

In-hospital outcomes

Mean Intensive Care Unit (ICU) and hospital stays were 3.6 ± 2.6 and 10.3 ± 5.9 days, respectively (Table 3). In-hospital rates of death, stroke, myocardial infarction, new permanent pacemaker implantation and acute kidney injury requiring dialysis were 2.4%, 1.2%, 0.8%, 2.4% and 1.2%, respectively (Supplementary Table 1). Three patients underwent re-intervention for early MVr failure (1.2%): 2 of them experienced recurrent severe MR resulting from ruptured neochordae and triangular resection suture dehiscence and the other patient had persistent SAM with severe MR. In the case of the ruptured neochordae, a new MVr was performed, consisting in adding a triangular resection. In the other two cases, MVR was performed. At discharge, 86% of the patients had no residual MR, 12% grade 1, 3% grade 2 to 3 and none grade 4. Mean MV gradient and LVEF were 4.3 ± 1.7 mmHg and 57.2 ± 8.6%, respectively.

One-year outcomes

Among the patients who underwent successful MVr at the index intervention and who were discharged (n=243), the one-year follow-up was 99.2% complete (2 foreign patients returned to their country of origin after surgery and were excluded from the analysis, Table 4). No additional death occurred during this period. Four patients required reoperation for MVr failure (1.6%): 2 cases of infective endocarditis, of whom one was recurrent, and 2 partial prosthetic ring detachments. One case of anterior leaflet perforation

Table 1: Baseline characteristics.

	n=255
Age (years)	64.7 ± 12.3
Female gender	67 (26.3)
NYHA functional class	
I	28 (10.9)
II	147 (57.6)
III	62 (24.3)
IV	18 (7.1)
Atrial fibrillation	100 (39.2)
Cardiovascular risk factors	
High blood pressure	108 (42.4)
Tobacco smoking	85 (33.3)
Dyslipidemia	58 (22.7)
Diabetes mellitus	19 (7.5)
Other comorbidities	
Coronary artery disease	12 (4.7)
Previous PCI	4 (1.6)
Previous cardiac surgery	6 (2.4)
Previous stroke	13 (5.1)
COPD	21 (8.2)
eGFR <60 ml/min	26 (10.2)
MR severity	
Grade I	0
Grade II	0
Grade III	26 (10.2)
Grade IV	229 (89.8)
Mitral valve lesions	
Annular dilatation	133 (52.2)
Chordal rupture	163 (63.9)
Chordal elongation	32 (12.5)
Left ventricular ejection fraction (%)	61.6 ± 8.5
Pulmonary hypertension	108 (42.4)
Concomitant valvular diseases	
Moderate to severe aortic stenosis	8 (3.1)
Aortic regurgitation ≥ 3/4	18 (7.1)
Tricuspid regurgitation ≥ 3/4	24 (9.4)
Tricuspid annular dilatation	35 (13.7)
EuroScore II	1.9 ± 1.9

Values are expressed as n (%) or mean ± SD.
COPD: Chronic Obstructive Pulmonary Disease; eGFR: estimated Glomerular Filtration Rate; MR: Mitral Regurgitation; NYHA: New York Heart Association; PCI: Percutaneous Coronary Intervention
Pulmonary hypertension was defined as systolic pulmonary artery pressure ≥ 35 mmHg at rest or during exercise testing

due to infective endocarditis was amenable to a new repair using an autologous patch and a prosthetic ring replacement. The other 3 cases required MVR. Overall, nine patients experienced rehospitalizations for cardiovascular causes (3.7%). At one-year follow-up, 219 patients were in NYHA class 1 status (90.5%), 22 in class 2 (9.1%), one in class 3 (0.4%) and none in class 4 (Figure 2). Regarding MR correction, 180 (74.7%) patients exhibited no recurrent MR, 53 (22%) patients a grade 1, 7 (2.9%) patients a grade 2, one (0.4%) patient a grade 3 and none a grade 4 recurrence (Figure 3). Mean MV gradient and LVEF were 3.5 ± 1.3 mmHg and 59.8 ± 7.2%, respectively. Overall, the main composite outcome (grade ≥ 2 recurrent MR and/or MV reintervention in the first postoperative year) occurred in 15 patients (6.2%). In univariate analysis, preoperative NYHA functional status (p=0.002), pulmonary hypertension (p=0.01), LVEF (p=0.04), prosthetic ring size (p<0.0001), postoperative acute kidney injury (p=0.001), hospital stay (p=0.01), and MR grade at discharge (p<0.0001) were significantly associated with the main composite outcome (Table 5).

Discussion

DMR is the second most frequent valvular heart disease in the

Table 2: Operative data.

	n=255
CPB time (minutes)	84.4 ± 31.2
Aortic cross clamp time (minutes)	63.4 ± 25.1
Repair technique	
Quadrangular resection with annulus plication	128 (50.2)
Sliding plasty	6 (2.4)
Triangular resection	36 (14.1)
Commissural plication	17 (6.7)
Indentation closure	25 (9.8)
Gore-tex™ chordae	65 (25.5)
Chordae transfer	13 (5.3)
Alfieri	2 (0.8)
Annulus massive decalcification	8 (3.1)
Prosthetic ring size	
26	8 (3.1)
28	19 (7.5)
30	62 (24.3)
32	87 (34.1)
34	46 (18)
36	27 (10.6)
38	6 (2.4)
Mitral valve replacement	4 (1.6)
Concomitant procedure	
Atrial fibrillation ablation	69 (27.1)
Left atrial appendage closure	44 (17.3)
Tricuspid valve annuloplasty	58 (22.7)
Aortic valve surgery	13 (5.1)
Coronary artery bypass grafting	30 (11.8)

Values are expressed as n (%) or mean ± SD
CPB: Cardiopulmonary Bypass

Table 3: In-hospital outcomes.

	n=251
ICU stay (days)	3.6 ± 2.6
Hospital stay (days)	10.3 ± 5.9
Deaths	6 (2.4)
Reoperation for bleeding	27 (10.8)
Stroke	3 (1.2)
Myocardial infarction	2 (0.8)
Atrial fibrillation	125 (49.8)
New permanent pace-maker	6 (2.4)
Acute kidney injury	25 (9.9)
Dialysis	3 (1.2)
Pneumonia	25 (9.9)
Mitral valve reoperation	
Mitral valve replacement	2 (0.8)
New mitral valve repair	1 (0.4)
MR severity at discharge	
None	216 (86)
Grade I	30 (12)
Grade II	3 (1.2)
Grade III	2 (0.8)
Grade IV	0
Mitral valve mean gradient (mmHg)	4.3 ± 1.7
LVEF at discharge (%)	57.2 ± 8.6

Values are expressed as n (%) or mean ± SD
ICU: Intensive Care Unit; LVEF: Left Ventricular Ejection Fraction; MR: Mitral Regurgitation

western countries, for whom MVr is considered as the gold-standard therapy when surgery is indicated [1-3]. MV annuloplasty is pivotal in surgical MVr. It aims to restore the normal MA geometry, avoid further dilatation and maintain leaflet coaptation. The final goal is to prevent a post-operative recurrent MR, known to impair LV remodeling and survival [4-6]. With its semi-rigid and saddle-shaped

Table 4: One-year outcomes.

	(n = 241)
Death	0
Stroke	1 (0.4)
Atrial fibrillation	38 (15.8)
Infective endocarditis	2 (0.8)
Rehospitalization	9 (3.7)
Reoperation New mitral valve repair Mitral valve replacement	4 (1.6) 1 (0.4) 3 (1.2)
NYHA functional class I II III IV	 218 (90.5) 22 (9.1) 1 (0.4) 0 (0)
Echocardiographic MR severity None Grade I Grade II Grade III Grade IV	 180 (74.7) 53 (22) 7 (2.9) 1 (0.4) 0
Mitral valve mean gradient (mmHg)	3.5 ± 1.3
Left ventricular ejection fraction (%)	59.8 ± 7.2

Values are expressed as n (%) or mean ± SD
MR: Mitral Regurgitation; NYHA: New York Heart Association

features, the Memo 3D ring is designed to offer uniform annular force distribution, optimal leaflet coaptation and, by folding MA dynamics throughout the cardiac cycle, reduced mitral leaflet stress [7-14]. Overall, our findings show that MVr with the Memo 3D annuloplasty ring in patients with DMR was associated with satisfying midterm results regarding MR correction and functional improvement at one-year follow-up. The in-hospital mortality observed in our study (2.4%, n=6) is in line with those reported in previous series, ranging from 0.2% to 5.4% [17-20]. In our series, 2 thirds of the in-hospital deaths were due to non-cardiac causes, highlighting that patient selection and perioperative management are key issues, even in a population considered to be at low surgical risk (EuroSCORE II 1.9 ± 1.9%). For the patients who died in the postoperative period, mean age was 73.2 ± 7.8, to put into perspective with the 5.4% 30-day mortality rate reported in a recent study on MVr for DMR in patients ≥ 75 [18]. However, a recent meta-analysis comparing MVr (2,950 patients) and MVR (1,252 patients) across 12 studies concluded that early mortality was higher in the MVR group (risk ratio =4.51) regardless of patients' age [21]. Moreover, 5 of these 6 patients underwent combined valvular procedures, which are known to be higher risk conditions. Likewise, the rates of stroke (1%), myocardial infarction (1%), new permanent pacemaker implantation (2%) and acute kidney injury requiring dialysis (1%) observed in our series were low and compare favorably with the recent literature [17-19]. During the first postoperative year, the very low rates of additional death (n=0) and cerebral events (n=1) have to be confirmed in a longer-follow-up. However long-term outcomes of MVr in DMR are widely known to be excellent, improving survival and reducing the valve-related complications compared to MVR [17]. Reporting their experience with the Physio II ring (Edwards Lifesciences, Irvine, CA, USA) in isolated MVr for DMR (no combined procedure apart from AF ablation and left atrial appendage closure, mean age 54.8 years, mean EuroSCORE II 2.7%), Noack observed 30-day mortality and 4-year survival of 0.4% and 98.5%, respectively [22]. In their one-year follow-up of 151 patients implanted with the Profile 3D ring (Medtronic,

Table 5: Composite outcome: univariate analysis.

	All (n=243)	No composite outcome (n=228)	Composite outcome (n=15)	p
Baseline characteristics				
Age (years)	64.5 ± 12.4	64.5 ± 12.1	63.7 ± 16.3	0.93
Female gender	63 (25.9)	61 (26.8)	2 (13.3)	0.25
NYHA functional class I II III IV	 28 (11.5) 139 (57.2) 59 (24.3) 17 (7)	 26 (11.4) 136 (59.6) 51 (22.4) 15 (6.6)	 2 (13.3) 3 (20) 8 (53.3) 2 (13.3)	0.002
Atrial fibrillation	96 (39.5)	88 (38.6)	8 (53.3)	0.26
Cardiovascular risk factors High blood pressure Tobacco smoking Dyslipidemia Diabetes mellitus	 103 (42.4) 81 (33.3) 55 (22.6) 17 (6.9)	 98 (42.9) 76 (33.3) 51 (22.4) 16 (7)	 5 (33.3) 5 (33.3) 4 (26.7) 1 (6.7)	 0.46 1 0.7 0.96
Other main comorbidities Previous coronary disease Previous PCI Previous cardiac surgery Previous stroke COPD Renal failure	 10 (4.1) 2 (0.8) 6 (2.5) 12 (4.9) 19 (7.8) 25 (10.3)	 10 (4.4) 2 (0.9) 5 (2.2) 12 (5.3) 17 (7.5) 22 (9.6)	 0 0 1 (6.7) 0 2 (13.3) 3 (20)	 0.41 0.72 0.28 0.36 0.41 0.2
EuroScore II	1.9 ± 1.9	1.9 ± 1.9	2.5 ± 1.7	0.05
MR severity Grade I Grade II Grade III Grade IV	 0 0 25 (10.3) 218 (89.7)	 0 0 25 (11) 203 (89)	 0 0 0 15 (100)	 0.18
Mitral valve lesions Annular dilatation Chordal rupture Chordal elongation	 129 (53.1) 155 (63.8) 32 (13.2)	 122 (53.5) 148 (64.9) 32 (14)	 7 (46.7) 7 (46.7) 0	 0.6 0.15 0.12
LVEF (%)	61.7 ± 8.4	61.9 ± 8.3	58.6 ± 9.2	0.04

Pulmonary hypertension	101 (41.6)	90 (39.5)	11 (73.3)	0.01
Operative data				
Emergency	11 (4.5)	10 (4.4)	1 (6.7)	0.68
CPB time (min)	83.6 ± 31	83.1 ± 30.7	90.9 ± 35.7	0.26
Aortic cross clamp time (min)	62.7 ± 24.7	62.4 ± 24.1	67.8 ± 33.2	0.6
Repair technique Quadrangular resection with annulus plication Sliding plasty Triangular resection Commissural plication Indentation closure Gore-tex chordae Chordae transfer Alfieri	125 (51.4) 6 (2.5) 34 (14) 16 (6.6) 25 (10.3) 61 (25.1) 13 (5.3) 2 (0.8)	122 (53.5) 6 (2.6) 33 (14.5) 13 (5.7) 21 (9.2) 56 (24.6) 12 (5.3) 1 (0.4)	3 (20) 0 1 (6.7) 3 (20) 4 (26.7) 5 (33.3) 1 (6.7) 1 (6.7)	0.01 0.52 0.4 0.03 0.03 0.45 0.81 0.3
Prosthetic ring size 26 28 30 32 34 36 38	 8 (3.3) 16 (6.6) 59 (24.3) 85 (35) 46 (18.9) 24 (10) 5 (2.1)	 8 (3.5) 16 (7) 55 (24.1) 80 (35.1) 41 (18) 23 (10.1) 5 (2.2)	 0 0 4 (26.7) 5 (33.3) 5 (33.3) 1 (6.7) 0	<0.0001
Concomitant procedure Atrial fibrillation ablation Left atrial appendage closure Tricuspid valve annuloplasty Aortic valve surgery CABG	 67 (27.6) 42 (17.3) 51 (21) 12 (4.9) 30 (12.3)	 61 (26.8) 38 (16.7) 47 (20.6) 10 (4.4) 30 (13.2)	 6 (40) 4 (26.7) 4 (26.7) 2 (13.3) 0	 0.27 0.32 0.58 0.06 0.13
In-hospital outcomes				
ICU stay (days)	3.6 ± 2.6	3.5 ± 2.6	4.1 ± 2.6	0.31
Hospital stay (days)	10.3 ± 5.6	10 ± 5.4	15 ± 7.8	0.01
Myocardial infarction	1 (0.4)	1 (0.4)	0	0.8
Atrial fibrillation	124 (51)	115 (50.4)	9 (60)	0.47
New permanent pace-maker	5 (2.1)	5 (2.2)	0	0.56
Reoperation for bleeding	25 (10.3)	23 (10.1)	2 (13.3)	0.69
Acute kidney injury Dialysis	23 (9.5) 2 (0.8)	18 (7.9) 2 (0.9)	5 (33.3) 0	0.001 0.72
Pneumonia	24 (9.9)	22 (9.7)	2 (13.3)	0.64
MR severity at discharge None Grade I Grade II Grade III Grade IV	 208 (85.6) 30 (12.3) 3 (1.2) 2 (0.8) 0	 201 (88.2) 25 (11) 2 (0.9) 0 0	 7 (46.7) 5 (33.3) 1 (6.7) 2 (13.3) 0	 <0.0001
MV mean gradient (mmHg)	4.3 ± 1.7	4.3 ± 1.7	3.8 ± 2.3	0.31
LVEF at discharge (%)	57.2 ± 8.4	57.5 ± 8.3	54 ± 9.3	0.14

Values are expressed as n (%) or mean ± SD

The composite outcome was defined as grade ≥ 2 recurrent MR and/or MV reintervention in the first postoperative year

CABG: Coronary Artery Bypass Grafting; COPD: Chronic Obstructive Pulmonary Disease; CPB: Cardiopulmonary Bypass; ICU: Intensive Care Unit; LVEF: Left Ventricular Ejection Fraction; MR: Mitral Regurgitation; MV: Mitral Valve; MVR: Mitral Valve Replacement; NYHA: New York Heart Association; PCI: Percutaneous Coronary Intervention

Minneapolis, MN, USA), Doll reported 2 in-hospital deaths (1.4%) and one additional death thereafter [23]. Regarding MR correction, beside the 4 cases of intraoperative bail-out MVR, 3 patients experienced early MVr failure and required a reintervention during the index hospitalization (1%), being amenable to a new MVr in one case and requiring MVR in the two others. In the first postoperative year, 4 more patients required a reintervention (1%), including 2 cases of infective endocarditis. A re-repair procedure was performed in one case and MVR in the 3 others. This 1-year reintervention rate of 2% is in line with the recent literature on MVr in DMR [17,20]. Likewise, Noack reported 1-year and 4-year freedom from MV reintervention of 96.2% and 94%, respectively, with the Physio II ring, whereas Doll mentioned 2 MVR (1.4%) in the first-year post repair with Profile 3D (one case of ring detachment and one SAM on progressive Barlow disease) [22,23]. Most of our reintervention patients (5 out of 7) experienced procedure-related failures (suture dehiscence, neochordae rupture, ring detachment), which has been demonstrated to occur earlier than valve-related failures [24]. At the one-year follow-up, 8 patients (3.3%) exhibited grade ≥ 2 recurrent MR and overall, 15 patients had experienced the composite outcome (MV reintervention and/or grade ≥ 2 recurrent MR) at this timepoint (6.2%). After univariate analysis, the preoperative characteristics mainly associated with the composite outcome were NYHA status (p=0.002), pulmonary hypertension (p=0.01) and LVEF (p=0.04).

Supplementary Table 1: Causes of in-hospital death.

Patient	Cause of death	Day
1	Septic shock/pneumopathy	7
2	Stroke	10
3	Septic shock/unknown origin	38
4	Right heart failure on ventricular septal defect post myomectomy: Early reintervention for correction, extracorporeal life support	6
5	Cardiogenic shock/unknown origin	1
6	Stroke	0

These findings are consistent with recent publications and they emphasize that more advanced stages of the disease, characterized by impaired LV function, heart failure symptoms and pulmonary hypertension negatively impact the outcomes of MVr [25-27]. These observations advocate for earlier surgical correction of DMR (before the onset of symptoms and LV dysfunction), that is widely endorsed by recent guidelines [2,3]. Otherwise, prosthetic ring diameter correlated well with the composite outcome ($p<0.00001$) and this aligns with the fact that the success rate of MVr partly lies in the right sizing of the prosthetic annulus diameter, avoiding residual MR as well as obstruction or over tension on the leaflets. MA dynamics after MVr with an annuloplasty ring still remains a matter of further interest. Lastly, most of the patients had no or mild residual MR at discharge. Nevertheless, any degree of postoperative MR was associated with the composite outcome ($p<0.0001$), which is consistent with a recent study demonstrating that even mild intraoperative residual MR was a strong predictor of significant recurrent MR after MVr for DMR [26]. Finally, the overall 1-year improvement of functional status was satisfying with more than 90% of the population being asymptomatic and most of the others having only mild symptoms.

Limitations

Findings of this study should be interpreted with caution due to several limitations, including its short follow-up, as well as its retrospective, observational and monocentric design. Most of the procedures were performed in this period by two surgeons with a mean MVr volume above 30 to 40 per year per surgeon, which is of importance given the impact of expertise on outcomes and could introduce some bias. Moreover, echocardiographic follow-up was obtained through outpatient cardiologists in most of the cases, which explains the scarcity of parameters available for analysis and introduces concerns regarding examiner-related bias. Finally, prospective randomized trials are needed to compare clinical outcomes and hemodynamics features of the different available annuloplasty ring devices.

Conclusion

Our study suggests that MVr with the Memo 3D semi-rigid prosthetic ring achieved satisfying and sustainable MV function, resulting in markedly improved functional status at one-year follow-up in patients with severe DMR. Further investigation is warranted to determine both the long-term outcomes of these procedures and the dynamic features of the device, especially when compared to other rings.

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