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Long-term outcomes and quality of life following implementation of dedicated mitral valve Heart Team decisions for patients with severe mitral valve regurgitation in tertiary cardiovascular care center

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Abstract

Background: *This study was purposed to investigate which treatment strategy was associated with the most favourable prognosis for patients with severe mitral regurgitation (MR) following Heart Team (HT)-decisions implementation.*

Methods: *In this retrospective study, long-term outcomes of patients with severe MR qualified after HT discussion to: optimal medical treatment (OMT) alone, OMT and MitraClip (MC) procedure or OMT and mitral valve replacement (MVR) were evaluated. The primary endpoint was defined as cardiovascular (CV) death and the secondary endpoints included all-cause mortality, myocardial infarctions (MI), strokes, hospitalizations for heart failure exacerbation and CV events during a mean (standard deviation [SD]) follow-up of 29 (15) months.*

Results: *From 2016 to 2019, 176 HT meetings were held and a total of 157 participants (mean age [SD] = 71.0 [9.2], 63.7% male) with severe MR and completely implemented HT decisions (OMT, MC or MVR for 53, 58 and 46 patients, respectively) were included into final analysis. Comparing OMT, MC and MVR groups statistically significant differences between the implemented procedures and occurrence of primary and secondary endpoints with the most frequent in OMT-group were observed ($p < 0.05$). However, for interventional strategy MC was non-inferior to MVR for all endpoints ($p > 0.05$). General health status assessed at the end of follow-up were significantly the lowest for MVR, then for MC and the highest for OMT-group ($p < 0.01$).*

Conclusions: *In the present study it was demonstrated that after careful HT evaluation of patients with severe MR at high risk of surgery, percutaneous strategy (MC) can be considered as equivalent to surgical treatment (MVR) with non-inferior outcomes.* (Cardiol J 2024; 31, 1: 62–71)

Key words: Heart Team, mitral regurgitation, heart failure, mitral valve replacement, MitraClip

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Introduction

Mitral regurgitation (MR) — the most common valvular heart disease (VHD) in adults and the second most frequent indication for valve surgery in Europe — despite enormous development of medicine and pharmacotherapy, still remains a pressing problem of today's cardiology, associated with the development of heart failure (HF), poor prognosis and increased mortality [1–3]. Hence the concept of multi-specialist group — the Heart Team (HT) — responsible for management of patients who are at high surgical risk or qualified only for medical therapy is still evolving. With the development of new technologies and novel approaches many patients can be successfully treated, but advanced age and/or multiple co-morbidities often make it difficult or even impossible to obtain treatment goals of care in real clinical practice. Therefore, the necessity of HT creation was recognized and the role of HT in decisions-making for patients with VHD, including MR was emphasized both in the European and American guidelines [2, 3]. An approach of a multidisciplinary experienced team, taking into account clinical, angiographic and echocardiographic data, risk stratification, long-term prognosis and patients preferences seems to be a rational tool when deciding on the best treatment method for each patient, burdened with many co-morbidities. However, the idea of HT is generally considered in the medical society as an optimal therapeutic option for "difficult" patients, its concept is still not yet widely adopted and the supportive data in the literature is insufficient and poorly proved. According to available literature, only two research papers regarding the influence of HT decisions on prognosis of MR-patients were revealed [4, 5]. Notwithstanding, the results of these two are ambiguous and require further confirmation. More evidence investigating HT consistency and significance of decisions making and performance on hard clinical endpoints are required. We believe that the obtained results and conclusions formulated will be supportive for emphasizing the evidence-based role of HT in real-life clinical practice and its further development in the field of cardiovascular medicine.

Methods

This single-center cohort study was conducted in the 1st Department of Cardiology, Medical University of Warsaw, a large third-degree academic center. A total number of 254 patients consulted for symptomatic, both primary (PMR) and secondary (SMR) MR during 176 HT meetings in 2016–2019 were enrolled in this retrospective study. The inclusion criteria were: aged ≥ 18 years and complete clinical, echocardiographic and angiographic characteristics. The exclusion criteria included the following: pregnancy/lactation, disseminated neoplastic process, life expectancy < 1 year, lack of informed, written consent. All of patients were presented to an experienced HT–council consisting of at least four specialists: general (conservative) cardiologist, echocardiographer, interventional cardiologist and cardiac surgeon. Patients were qualified after HT discussion to one of three main strategies: optimal medical treatment (OMT) alone, OMT and MitraClip (MC) procedure or OMT and mitral valve replacement (MVR). OMT was defined as use of drugs in a manner that provides an optimal reduction of signs and symptoms associated with mitral valve (MV) defect or secondary to subsequent HF. The degree of MR was assessed using echocardiographic criteria on a scale from 1 to 4, where 1+ was determined as faint opacification of the left atrium with clearing of contrast during each beat, while 4+ meant immediate, dense opacification of the left atrium with filling of the pulmonary veins. The severe MR in the present study was defined as grade 3+ or 4+ and effective regurgitant orifice (ERO) ≥ 0.40 cm^2 for severe PMR and ERO ≥ 0.20 cm^2 for severe SMR assessed by echocardiography (in accordance to European guidelines) [2]. The severity of HF symptoms was assessed using New York Heart Association (NYHA) classification, chronic kidney disease (CKD) defined as glomerular filtration rate (GFR) < 60 mL/min/1.73 m^2, anemia as hemoglobin level < 12 g/dL for women and < 14 g/dL for men, cancer — as active or up to 5 years prior and smoking — as active or in the past. Ultimately, after excluding non-eligible patients, the patients who died before decision implementation, did not consent with HT decision or loss of follow-up, 157 (61.8%) individuals with completely implemented HT decisions (OMT, MC, MVR — 53, 58, 46 patients, respectively) were included into the final analysis. As the primary endpoint the cardiovascular (CV) death was considered, while all-cause mortality, non-fatal myocardial infarctions (MI), non-fatal strokes, non-fatal hospitalizations for HF exacerbation and any CV events (including CV death, non-fatal MI, non-fatal stroke and non-fatal hospitalizations for HF exacerbation) per single patient were assessed as secondary endpoints. All participants were observed for occurrence of

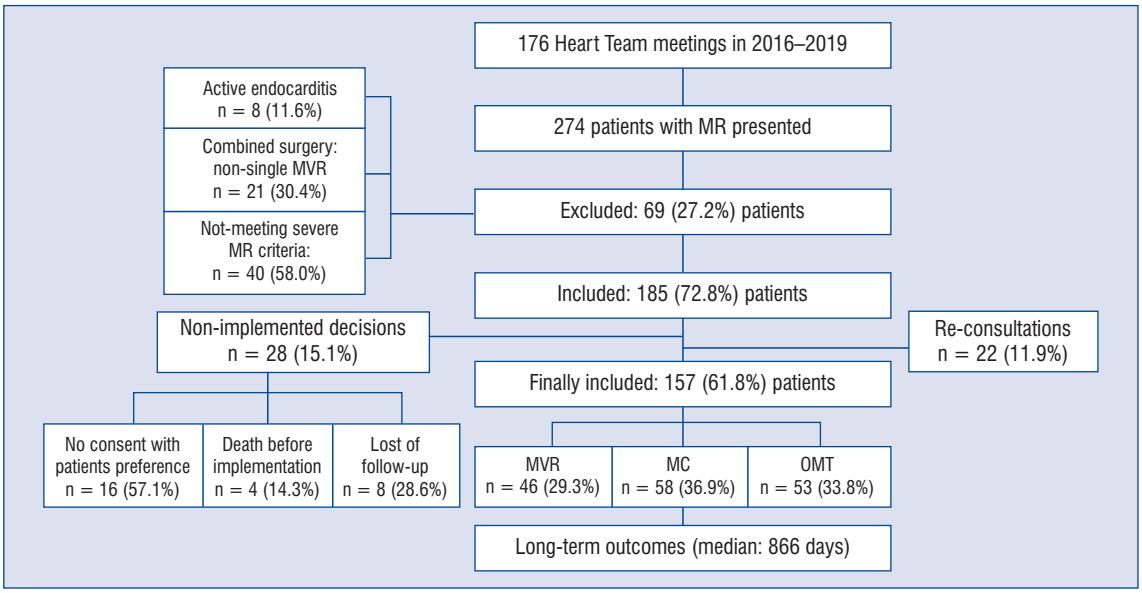

Figure 1. Study design; MR — mitral regurgitation; MVR — mitral valve replacement; MC — MitraClip; OMT — optimal medical therapy.

endpoints with mean ± standard deviation (SD) follow-up of 29 ± 15 months. The main outline of the study was presented in Figure 1. Additionally, general health status, using the short-form (SF)-36 questionnaire (totally and separately for physical component summary [PCS] and mental component summary [MCS]) before MVR, MC and HT discussion (for patients qualified for OMT) and at the end of follow-up for all living participants (31 December 2020) was assessed. Due to the observational nature of the study, an application to the ethical/institutional review board (IRB) for approval of the present study was unnecessary. All participants gave written informed consent for publication of study results.

Statistical analysis

The PQStat software (version 1.6.6, PQStat, Poznan, Poland) was used for statistical analysis. The normality of distribution for continuous variables was confirmed with the Shapiro–Wilk test. Categorical data were expressed as counts and percentages, while continuous data were presented as mean ± SD. The comparison between groups of patients qualified for individual treatment strategies was performed using χ^2 test and the statistical analysis was executed using one-way analysis of variance (ANOVA). To compare the outcomes for all strategies with each other, the hazard ratios (HRs) with 95% confidence intervals (95% CI) were calculated. Time to event analysis was performed using Kaplan–Meier curves. All p values (p) were given to at least two-sided and p value lower than 0.05 were considered statistically significant.

Results

Study population

From January 2016 to December 2019, 176 HT meetings were held and total of 157 patients with severe MR meeting inclusion and exclusion criteria with completely implemented HT decisions (100; 63.7%) male, age (years, mean ± SD) = 71.0 ± 9.2, body mass index (kg/m^2, mean ± SD) = 26.2 ± 4.8, 43 (27.4%) with primary MR, 154 (98.1%) with HF, NYHA (class, mean ± SD) = 3.50 ± 0.50, European System for Cardiac Operative Risk Evaluation II (EuroSCORE II, %, mean ± SD) = 7.71 ± 2.55 and given co-morbidities were followed up. The mean delay time from HT decision to implementation was: 59 ± 9 and 31 ± 6 days for MC and MVR, respectively (p = 0.001). As regards statistically significant differences between MVR, MC and OMT groups, patients qualified for OMT were older than those with implemented MVR or MC, primary MR was the most common in MVR-group, while participants with MC had the most severe symptoms (assessed by NYHA class). Diabetes, atrial fibrillation (AF) and chronic obstructive pulmonary disease (COPD) were the most common in OMT-group, while CKD and history of previous coronary artery bypass grafting were most often

Table 1. Baseline clinical characteristics (n = 157).

	Overall (157)	MVR (46)	MC (58)	OMT (53)	P
Age [years]	71.03 ± 9.18	67.8 ± 8.86	71.1 ± 9.72	73.7 ± 11.05	0.02
Gender — male	100 (63.7%)	31 (67.4%)	37 (63.8%)	32 (60.4%)	0.77
BMI [kg/m^2]	26.22 ± 4.76	26.76 ± 6.04	25.23 ± 13.8	26.82 ± 3.95	0.47
Etiology — primary MR	43 (27.4%)	26 (56.5%)	8 (11.9%)	9 (17.0%)	< 0.001
Heart failure	154 (98.1%)	44 (95.7%)	58 (100.0%)	52 (98.1%)	0.28
NYHA	3.50 ± 0.50	3.39 ± 0.49	3.64 ± 0.48	3.47 ± 0.50	0.03
Coronary artery disease	114 (72.6%)	29 (63.0%)	45 (77.6%)	40 (75.5%)	0.22
Diabetes	73 (46.5%)	8 (17.4%)	31 (53.4%)	34 (64.2%)	<0.001
Hypertension	148 (94.3%)	42 (91.3%)	55 (94.8%)	51 (96.2%)	0.57
Previous stroke/TIA	42 (26.8%)	14 (30.4%)	15 (25.9%)	13 (24.5%)	0.79
Atrial fibrillation	48 (30.6%)	8 (17.4%)	18 (31.0%)	22 (41.5%)	0.03
Previous MI	102 (65.0%)	24 (52.2%)	41 (70.7%)	37 (69.8%)	0.10
Previous PCI	111 (70.7%)	28 (60.9%)	43 (74.1%)	40 (75.5%)	0.22
Previous CABG	36 (22.9%)	4 (8.7%)	17 (29.3%)	15 (28.3%)	0.02
Chronic kidney failure	136 (86.6%)	33 (71.7%)	55 (94.8%)	48 (90.6%)	0.001
Anemia	122 (77.7%)	34 (73.9%)	47 (81.0%)	41 (77.4%)	0.69
Dyslipidemia	134 (85.4%)	39 (84.8%)	51 (87.9%)	44 (83.0%)	0.76
COPD	46 (29.3%)	6 (13.0%)	17 (29.3%)	23 (43.4%)	0.004
Cancer	36 (22.9%)	7 (15.2%)	13 (22.4%)	16 (30.2%)	0.21
Smoking	135 (86.0%)	40 (87.0%)	52 (89.7%)	43 (81.1%)	0.43
EuroSCORE II [%]	7.71 ± 2.55	6.65 ± 2.79	8.13 ± 2.90	8.05 ± 1.81	0.004
Medications at discharge:					
ACEI/ARB	143/152 (91.45%)	37/42 (88.10%)	51/57 (89.47%)	51/53 (96.23%)	0.16
ARNI	7/152 (4.61%)	2/42 (4.76%)	3/57 (5.26%)	2/53 (3.77%)	0.93
Beta–blockers	133/152 (87.50%)	34/42 (80.95%)	50/57 (87.72%)	49/53 (92.45%)	0.25
Loop diuretics agents	144/152 (94.74%)	38/42 (90.48%)	53/57 (92.98%)	53/53 (100.0%)	0.09
Aldosterone antagonists	75/152 (49.34%)	16/42 (38.10%)	28/57 (49.12%)	31/53 (58.49%)	0.14

MVR — mitral valve replacement; MC — MitraClip; OMT — optimal medical therapy; BMI — body mass index; MR — mitral regurgitation; NYHA — New York Heart Association; TIA — transient ischemic attack; MI — myocardial infarction; PCI — percutaneous coronary intervention; CABG — coronary artery bypass grafting; COPD — chronic obstructive pulmonary disease; EuroSCORE II — European System for Cardiac Operative Risk Evaluation II; ACEI — angiotensin-converting enzyme inhibitors; ARB — angiotensin receptor blockers; ARNI — angiotensin receptor-neprilysin inhibitors

found in MC-group ($p < 0.05$ for all). Participants qualified for MVR had the lowest perioperative risk of death as assessed using the EuroSCORE II scale ($p < 0.05$) — detailed in Table 1.

Echocardiographic parameters

All patients were assessed by echocardiography — from OMT-group at the time of HT discussion and from MVR- and MC-groups before and after intervention (at the time of discharge from the hospital). Statistically significant differences in echocardiographic parameters before HT decision implementation were observed in the following: ejection fraction of left ventricle (LVEF) with the highest in MVR-group, the diameter of left ventricle (LV) (assessed by left ventricular end-diastolic dimension [LVEDD]) and ERO with the lowest in MVR-group and mean mitral valve gradient (MVG) — the lowest in MC-group ($p < 0.05$ for all). The results of echocardiographic parameters assessed after MVR or MC implementation differ between these two groups for residual central MR degree ≥ 2 and paravalvular leak, ERO, MR volume, maximum and mean MVG and were significantly better in MVR-group ($p < 0.05$ for all) — as detailed in Table 2.

Endpoints

In-hospital mortality did not significantly differ between MVR and MC strategy (4 [8.7%] vs. 1 [1.7%]; $p = 0.10$). The occurrence of primary endpoint was statistically the most frequent in OMT-group (20 patients, 37.7%), while in MVR and

Table 2. Echocardiographic parameters before and after Heart Team decisions implementation.

	BEFORE Heart Team decisions implementation				P
	Overall (157)	MVR (46)	MC (58)	OMT (53)	
LVEF [%]	33.09 ± 9.54	42.43 ± 6.09	30.3 ± 11.1	30.3 ± 7.1	< 0.001
LVEDD [cm]	6.40 ± 0.66)	6.24 ± 0.65	6.36 ± 0.55	6.61 ± 0.66	0.03
MR [degree]	3.36 ± 0.48	3.35 ± 0.39	3.34 ± 0.53	3.38 ± 0.46	0.76
ERO [cm^2]	0.39 ± 0.09	0.37 ± 0.08	0.39 ± 0.11	0.42 ± 0.08	0.01
MR volume [mL/beat]	49.58 ± 12.71	48.50 ± 11.11	50.77 ± 17.33	49.46 ± 9.44	0.85
Max MVG [mmHg]	18.29 ± 8.27	17.17 ± 7.54	18.23 ± 6.24	19.24 ± 10.24	0.45
Mean MVG [mmHg]	5.80 ± 2.45	6.19 ± 2.29	4.12 ± 1.41	7.31 ± 2.36	< 0.001
	AFTER Heart Team decisions implementation				P
	MVR (42)		MC (57)		
Central MR degree ≥ 2	0 (0.0%)		8 (14.04%)		0.01
Paravalvular leak	3 (7.1%)		14 (24.56%)		0.02
ERO [cm^2]	0.12 ± 0.01		0.20 ± 0.08		< 0.001
MR volume [mL/beat]	15.40 ± 5.28		23.23 ± 7.93		< 0.001
Max MVG [mmHg]	6.64 ± 4.14		10.28 ± 5.90		< 0.001
Mean MVG [mmHg]	2.19 ± 0.94		3.02 ± 1.34		0.01

BEFORE — for MVR and MC — before procedure and for OMT — during Heart Team consultation; AFTER — after implemented procedure (MVR and MC); MVR — mitral valve replacement; MC — MitraClip; OMT — optimal medical therapy; LVEF — left ventricular ejection fraction; LVEDD — left ventricular end-diastolic dimension; MR — mitral regurgitation; ERO — effective regurgitant orifice; MVG — mitral valve gradient

Table 3. Primary and secondary endpoints.

	MVR (46 patients)	MC (58 patients)	OMT (53 patients)	P
Primary endpoint				
CV death	7 (15.2%)	10 (17.2%)	20 (37.7%)	0.01
Secondary endpoints				
All-cause mortality	10 (21.7%)	14 (24.1%)	29 (54.7%)	< 0.01
Non-fatal MI	2 (4.3%)	3 (5.2%)	9 (17.0%)	0.04
Non-fatal stroke	4 (8.7%)	3 (5.2%)	11 (20.8%)	0.03
Non-fatal hospitalizations for HF	11 (23.9%)	24 (41.4%)	44 (83.0%)	< 0.01
CV events/one patient	19 (41.3%)	34 (58.6%)	51 (96.2%)	< 0.01
In-hospital mortality	4 (8.7%)	1 (1.7%)	–	0.10

Hazard ratios (HR) with 95% confidence intervals (CI) comparing all strategies with each other (HR [95% CI]; P): **In-hospital mortality:** MC vs. MVR (0.2 [0.03–1.10]; 0.10); **CV death:** MC vs. MVR (1.13 [0.44–2.56]; 0.78), OMT vs. MC (2.19 [0.69–3.07]; 0.01), OMT vs MVR (2.48 [0.69–3.53]; 0.01); **all-cause mortality:** MC vs. MVR (1.11 [0.55–2.41]; 0.78), OMT vs. MC (2.27 [0.70–2.49]; < 0.01), OMT vs. MVR (2.52 [0.77–2.99]; < 0.01); **non-fatal MI:** MC vs. MVR (1.19 [0.27–5.03]; 0.85), OMT vs. MC (3.28 [0.55–6.40]; 0.05), OMT vs. MVR (3.91 [0.58–8.31]; 0.05); **non-fatal stroke:** MC vs. MVR (0.59 [0.16–2.24]; 0.48), OMT vs. MC (4.01 [0.69–6.13]; 0.01), OMT vs. MVR (2.39 [0.38–4.02]; 0.01); **non-fatal hospitalizations for HF:** MC vs. MVR (1.73 [0.88–2.78]; 0.06), OMT vs. MC (2.0 [0.99–2.75]; < 0.01), OMT vs. MVR (3.47 [1.47–4.52]; < 0.01); **CV events/one patient:** MC vs. MVR (1.42 [0.59–1.63]; 0.08), OMT vs. MC (1.64 [1.05–2.52]; < 0.01), OMT vs. MVR (2.33 [0.95–2.67]; < 0.01)
MVR — mitral valve replacement; MC — MitraClip; OMT — optimal medical therapy; CV — cardiovascular; MI — myocardial infarction; HF — heart failure

MC groups — 7 (15.2%) and 10 (17.2%) patients, respectively (p = 0.01). Additionally, MVR and MC were found to be significantly superior to OMT for all secondary endpoints (p < 0.05 for all endpoints) — detailed in Table 3. However, for interventional strategy — no statistically significant differences between MVR and MC outcomes were observed (p > 0.05 for all endpoints). The Kaplan-Meier curves for primary and secondary endpoints were presented in Figure 2.

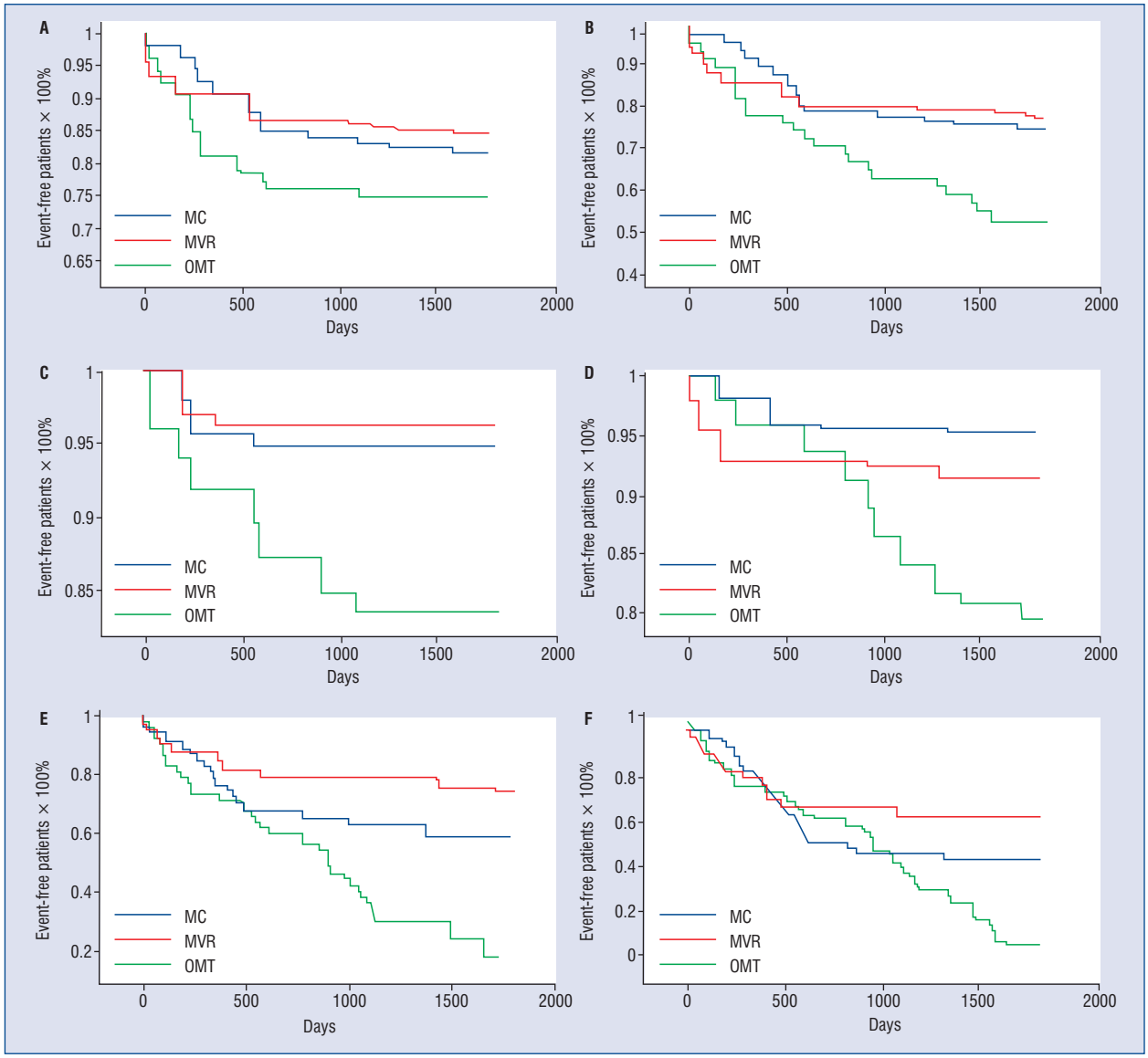

Figure 2. The Kaplan-Meier curves for endpoints; **A.** Cardiovascular deaths; **B.** Overall mortality; **C.** Non-fatal myocardial infarction; **D.** Non-fatal strokes; **E.** Non-fatal hospitalizations for heart failure exacerbation; **F.** Cardiovascular events; MC — MitraClip; MVR — mitral valve replacement; OMT — optimal medical therapy.

Quality of life

General health status before implementing HT decisions — PCS, MCS and total — did not statistically differ between treatment groups ($p > 0.05$ for all). At the end of follow-up the results of PCS, MCS and total for all living participants were significantly the lowest for MVR, then for MC and were the highest for OMT-group ($p < 0.01$) — detailed in Table 4. According to the Polish version of the questionnaire, with a maximum of 103 points for PCS and 68 points for MCS (171 points — total), the highest point value means the lowest quality of life assessment, while the lowest point value indicates the highest level of quality of life [6, 7].

Discussion

Mitral regurgitation caused by any structural or functional dysfunction of MV leaflets, MV apparatus or LV remodeling is a common problem of patients admitted to cardiology divisions all over the world [1–3, 8]. Regardless of the mechanism of this defect, MR results in the progression of HF symptoms, deterioration of the quality of life

Table 4. The quality of life before and after Heart Team (HT) decisions implementation.

	MVR (46 patients)	MC (58 patients)	OMT (53 patients)	P value
Physical component summary				
Before MVR, MC, HT discussion	76.15 ± 15.60%	77.84 ± 15.61	79.58 ± 11.89	0.50 (p for MVR vs. MC; MVR vs. OMT; MC vs. OMT: 0.58; 0.22; 0.51, respectively)
After MVR, MC, HT discussion — at the end of follow up	60.15 ± 14.49	68.34 ± 15.93	83.08 ± 9.44	< 0.01 (p for MVR vs. MC; MVR vs. OMT; MC vs. OMT: < 0.01 for all)
Mental component summary				
Before MVR, MC, HT discussion	51.07 ± 10.17	52.05 ± 8.43	53.81 ± 8.29	0.30 (p for MVR vs. MC; MVR vs. OMT; MC vs. OMT: 0.59; 0.14; 0.27, respectively)
After MVR, MC, HT discussion — at the end of follow up	43.07 ± 8.79	46.55 ± 8.82	57.31 ± 6.34	< 0.01 (p for MVR vs. MC; MVR vs. OMT; MC vs. OMT: 0.06; < 0.01; < 0.01, respectively)
Total				
Before MVR, MC, HT discussion	127.22 ± 20.85	129.90 ± 19.14	133.40 ± 12.11	0.22 (p for MVR vs. MC; MVR vs. OMT; MC vs. OMT: 0.50; 0.07; 0.26, respectively)
After MVR, MC, HT discussion — at the end of follow up	103.22 ± 17.42	114.90 ± 15.99	140.40 ± 8.84	< 0.01 (p for MVR vs. MC; MVR vs. OMT; MC vs. OMT: < 0.01 for all)

MVR — mitral valve replacement; MC — MitraClip; OMT — optimal medical therapy

and increased mortality, even despite the surgical and pharmacological treatment applied [1–3]. With an aging population, living with more chronic medical conditions, the frequency of this disease will continue to grow, as will be asking about new treatment options. Current evidence concerning survival outcomes of MR-patients qualified for different treatment modalities remains scarce, and although multiple reports have published survival data, only a few have compared outcomes post MC to surgical treatment. So far, only one randomized controlled trial (RCT), the Endovascular Edge-to-Edge Repair Study (EVEREST) II and some observational studies evaluating prognosis after conventional surgery versus MC were reported. In the EVEREST II trial [9] patients with grade 3/4+ MR were randomly assigned to MC or conventional MV surgery in a 2:1 ratio (178:80). At 5 years the rate of the composite endpoint of freedom from death, surgery for residual MR, or 3/4+ MR in the intention-to-treat population was 44.2% vs. 64.3% in the MC and surgical groups, respectively (p = 0.01). Five-year mortality rates were 20.8% and 26.8% (p = 0.4) for percutaneous repair and surgery, respectively, whereas in multivariable analysis, treatment strategy was not associated with survival.

In the recently updated meta-analysis of Oh et al. [10] (9 studies including the EVEREST II trial) demonstrating outcomes after MR-treatment, MC--patients (n = 533) as compared to surgical group — MVR (n = 644) had at baseline more comorbidities, further — residual moderate-to-severe MR was more frequent in MC-cohort both at discharge (OR = 2.81; p < 0.01) and at 5 years (OR = 2.46; p < 0.01) and the higher need for reoperation in MC-group at latest follow-up (OR = 5.28; p < 0.01) was observed. However, overall mortality was comparable between these two groups (p = 0.06) for a mean follow-up of 4.8 years.

Based on current European recommendations for MR-treatment the role of HT is poorly underlined with class IIb and level C, while in American guidelines with class IIa/b from nonrandomized trials [2, 3]. There is growing evidence confirming the multidisciplinary approach of HT for management of many CV diseases — coronary artery disease [11–15], aortic stenosis [16–20] and AF [21] which has demonstrated great merit. Only for the safety and efficacy of the HT concept in MR filling the gaps with evidence is still urgent, whereas only two papers on this issue are currently available in the literature [4, 5]. In the study of Heuts et al. [4] 158 patients with MR qualified by HT to different

treatment strategies 30-day mortality for surgery (isolated MVR and concomitant surgery — 67 patients), transcatheter intervention (MC or MVP — 20 patients) and conservative groups (71 patients) were 3 (4.4%), 0 (0.0%) and 3 (4.2%), respectively. Using the Kaplan-Meier curves at a median follow-up of 450 days for the various groups, a beneficial long-term survival for surgically treated patients was demonstrated [4]. In other research, Külling et al. [5] reported retrospective single-center cohort study of 400 patients treated for MR. As followed by HT decisions, 179 (44.8%) patients were treated using MC, 185 (46.2%) by MVP and 36 (9.0%) by MVR. Outcomes with a mean follow-up time of 32.2 ± 17.6 months revealed that patients treated with MVP had higher 4-year survival (HR 0.40; 95% CI 0.26–0.63; $p < 0.001$) and fewer combined endpoints [5]. The present research is one of the few studies involving the concept of HT for MR-patients and according to available literature, the first study in which the MR-patients quality of life following HT decisions and implementation was also assessed. Contrary to expectations created by guidelines for VHD [2, 3], where the surgical approach (MV-repair whenever possible) is a gold standard of treatment for MR-patients, in the current study the percentage of patients for whom surgical therapy following HT discussion was chosen and implemented was only 29.3%, while 36.9% received percutaneous therapy (MC) and 33.8% were disqualified from interventional strategy (OMT). What seems to be even more important, participants treated with MC compared with MVR-group were not statistically significant, but had lower in-hospital mortality, while MC strategy was non-inferior to MVR for primary and secondary endpoints. As expected, mainly participants with primary MR, acceptable valve anatomy and lower surgical risk were qualified for surgical treatment (MVR), while those with secondary MR and increased risk were treated with MC. Regardless the results obtained herein, and although all of treatment strategies were proven to be effective in reducing MR, it should be clearly emphasized that the efficacy of MVR, MC and OMT is highly dependent on patient selection. For individuals with primary MR (basically dysfunction of MV, commissural disease, perforations, clefts), mitral valve area < 3.0 cm^2, high mean MVG (> 5 mmHg), at early stage of LV remodeling, not at critically-high risk of cardiac surgery (i.e. LVEF > 30%, LVEDD < 7.0 cm, without severe pulmonary hypertension, end-stage renal disease or on dialysis), without bleeding/coagulation disorders (need for anticoagulation after MVR) and indications for concomitant surgery of other valve or coronary artery bypass grafting, the MVR is the preferred method of treatment. On the other side, there are severely burdened patients with a high risk of death associated with classical MVR. These of them with "disproportionate" MR (regurgitant volumes disproportionately higher than the degree of LV dilatation), with no calcification of MV, optimally mitral valve area > 3.0 cm^2 and mean MVG < 4 mmHg are likely to mainly benefit from a therapy targeted to MC. At this point, the incidence of iatrogenic atrial septal defect after MC procedure should be also stressed out. This kind of MC consequence, if persistent can lead to stroke, right-sided heart enlargement, worse tricuspid regurgitation, and a higher re-hospitalization rate for HF [22]. Finally, the present study had older patients with more advanced HF, NYHA class IV and severe tricuspid regurgitation who had a dismal prognosis and patients with "proportionate" MR (regurgitant volume totally commensurate to LV enlargement). These subgroups would likely benefit the most from strategies aimed at reducing LV size (i.e., OMT and cardiac resynchronization therapy) alone, not directed to MV apparatus. As the problem of patients with MR treatment becomes more challenging, new therapeutic strategies, such as percutaneous MVR (TMVR) will be a step towards more sufficient and safe treatment. Preliminary studies reported that TMVR by compassionate use of TMVR prostheses as valve-in-valve and valve-in ring was associated with lower-than-expected peri-interventional mortality and satisfactory outcomes in highly selected patients [23–25]. Undoubtedly, the results of the current study should be followed by further RCTs, however, it was demonstrated that after careful HT evaluation, percutaneous strategy (MC) can be considered as a comparably effective and safe to surgical treatment (MVR) for some subsets of patients with severe MR. This may have an impact on recommendations towards MC in subsequent VHD guidelines.

Limitations of the study

The main limitations of this study are its retrospective character, a small sample size, and single-center design. Above that, the decisions--making process must be assigned to our individual HT cooperation and cannot be considered as a general one. Additionally, the treatment results for used strategies were presented together for patients with primary and secondary MR, what it

does not make possible, is to clearly determine which therapeutic option is best for a given etiology. Moreover, patients with non-implemented decisions were not included into the final analysis, so data was not available on their follow-up.

Patients were not matched; hence comparison of groups should be considered with caution. Individuals qualified for interventional strategies differ significantly in some parameters, both clinical (especially the etiology of MR, diabetes, CKD and COPD) and echocardiographic (mostly LVEF and mean MVG), hence the obtained outcomes cannot be a contribution to formulating far-reaching and unquestionable conclusions.

Conclusions

The present study illustrates how the HT approach and decisions affect prognosis and the quality of life for patients with MR. It should be especially emphasized that for MR-patients choosing the best treatment method should never be individual and only HT seems to be a suitable tool to provide satisfactory outcomes and acceptable quality of life. Further research on this issue is required, but our initial results may state a cornerstone for the future.

Conflict of interest: None declared

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