After a 5-year follow-up, would you repair the mitral valve or replace it?

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Abstract

Background: Mitral valve repair (MVRe) is considered to have a superior outcome compared to replacement (MVRp) in patients with mitral valve regurgitation (MVR). It was the aim of the study to analyze the clinical results and identify risk factors for short and long-term mortality. **Methods:** In a single-center analysis, patients undergoing isolated mitral valve procedures from June 2010 to December 2016 were identified. These were subsequently homogenized using 10 baseline characteristics for propensity-score matching. Comparative analyses were performed for early and long-term results, using the adequate statistical tool, identifying risk factors for the investigated endpoints. **Results:** 241 patients were identified in the entire cohort. After matching, patients were divided into 2 groups of 64 in each. The median age was similar. There was significant interaction to early mortality risk of MV in patients with coronary artery disease (CAD) (OR 11.94, 95% CI: 1.49-285.92, P=0.04) and late mortality in patients with higher EuroSCORE II (HR 1.14, 95% CI: 1.06-1.23, P<0.001). 5-year survival was significantly higher in MVRe versus MVRp (90.06% vs. 79.54% respectively, P=0.04). **Conclusions:** We concluded MVRe to be associated with lower operative and 5-year mortality and good postoperative outcomes compared to patients undergoing MVRp. Concomitant CAD was identified as one of the risk factors for increasing the in-hospital mortality rate. There was no significant difference in rehospitalization over the follow-up period. MVRe should be the treatment of choice for severe MVR and should remain a central aspect in valve centers' treatment algorithms and quality measures.

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Running Head: Reconstruction versus Repair

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ABSTRACT:

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Conclusions: We concluded MVRe to be associated with lower operative and 5-year mortality and good postoperative outcomes compared to patients undergoing MVRp. Concomitant CAD was identified as one of the risk factors for increasing the in-hospital mortality rate. There was no significant difference in rehospitalization over the follow-up period. MVRe should be the treatment of choice for severe MVR and should remain a central aspect in valve centers' treatment algorithms and quality measures.

Introduction:

Severe mitral valve regurgitation (MVR) is common valvular heart disease with an unfavorable prognosis when left untreated (1, 2), and with a prevalence of 2% in the general population (3).

When studying mitral valve pathology and its surgical implications it is of necessity to assess the etiology of the disease. Acute MVR may occur due to rupture of the papillary muscle in patients with acute STEMI (4). It may also present due to disruption of different parts of the mitral valve apparatus via infective endocarditis or spontaneous chordal rupture in patients with degenerative mitral valve disease. When assessing patients with chronic MVR, it is critical to distinguish between chronic primary (degenerative) and chronic secondary (functional) MVR, as these conditions are unequal (4) with the subsequent implications for treatment.

Degenerative disease of the mitral valve represents 60-70% of patients undergoing surgery in industrialized nations (5) and is most commonly related to prolapse of the mitral valve with a spectrum of pre-existing conditions, ranging from a single prolapsing valve segment to diffuse myxomatous degeneration with bi-leaflet prolapse and annular dilatation (5, 6).

Treatment algorithms have been redefined in recent years as a result of the excellent outcomes of surgical repair with a recommendation of risk stratification and earlier intervention when the probability of durable repair is high and surgery can be undertaken by experienced teams with high repair rates and low operative mortality and morbidity (2, 4, 7). Numerous studies comparing mitral valve repair to replacement have demonstrated a possible survival benefit for repair, with excellent safety and durability. However, these findings are controversial in light of reports showing a benefit for preventing recurrence of MVR and rehospitalization when undergoing replacement, and in regard to present reports, there are no randomized studies asserting MV repair to be preferred to replacement (8). Nevertheless, some studies emphasized the advantages of repair due to its lower operative mortality (9-11).

Our study aims to assess our institutional results of mitral valve surgery classifying into repair and replacement groups, compare intra- and postoperative results over a time span of 9 years, identify possible risk factors influencing early and long-term results and analyze the databank to obtain information to facilitate the decision-making process in consideration of our results.

Methods:

Study design:

Between June 2010 and December 2016, 241 patients underwent an isolated mitral valve (MV) surgery in our center. Patients who had active endocarditis and/or MV stenosis were excluded. Propensity-score matching for 10 baseline characteristics was used (Tab 1). 128 patients were identified and classified into two groups; MV repair group (MVRe) and MV replacement group (MVRp), with 64 patients in each group respectively. The median follow-up was 5.5 years (0.003-9.101) after surgery. The Indication of surgery was moderate to severe MVR, and we classified the MV pathology based on the Carpentier classification (Cc).

Surgical techniques:

Surgery was performed with use of cardiopulmonary bypass using cold crystalloid cardioplegic arrest. Bicaval cannulation was used and exposition of the mitral valve was achieved via a bi-atrial vertical transseptal incision or via Waterston's incision. Moderate hypothermia (32–34°C) was used. In the repair group, the valve was corrected using the "respect" technique by insertion of 2–5 artificial Gore-Tex Neo-Chordae to re-suspend the prolapsing segments in the presence of chordal rupture or elongation, in addition to a supplement of remodeling annuloplasty. Neo-Chordae were used via a premeasured moveable loop technique (12) with ventricular placed knots. In forms of regurgitation not associated with chordal rupture or elongation, correction of MV was performed only by remodeling annuloplasty. The rings used were Carpentier Edwards Physio II Annuloplasty ring or Sorin Memo 3D ReChord Mitral Valve Annuloplasty ring. In select cases, cleft sutures were placed.

Echocardiography:

The diagnostic test for MVR was performed by echocardiography as a standard test in the initial evaluation of patients with known or suspected valvular heart disease.

Transesophageal echocardiograms were performed intraoperatively in all patients after the repair or replacement, whereas transthoracic echocardiograms were performed routinely within 30 days and after 3 years in all patients after surgery.

Statistical Analysis:

Categorical variables were presented as absolute numbers with percentages. Their distributions were compared between the groups with the chi-square test if its assumptions were met. Otherwise, we used Fisher's exact test. Due to skewed distributions, all continuous variables were presented as median values with quartiles in brackets. We compared their distributions between the groups with the Mann-Whitney test. The survival analysis was made with the use of the Kaplan-Meier method. Using Cox regression models and calculating hazard ratios and 95% confidence intervals, analyses of data were conducted to identify risk factors for mortality in 30 days and 5 years. The survival functions of the analyzed groups were compared with the log-rank test. Overall, p-values <0.05 were considered statistically significant. For the statistical analysis, we used the R software v. 4.0.3. (Foundation for Statistical Computing, Vienna, Austria), as well as IBM SPSS v. 27.0.

Study end-points:

A primary end-point in this study was defined as all-cause mortality within 5 years, calculated from the date of surgery. Secondary end-points were re-operation, endocarditis and/or mortality within 30 days, 1, 3 and 5 years after surgery.

Results:

241 patients underwent isolated mitral valve surgery in our center. Propensity-score matching identified 128 patients, which were classified into two groups; MV repair group (MVRe) and replacement group (MVRp) with 64 patients in each group.

Patients' characteristics:

The median age of patients undergoing MVRe was 70.50 (42–86) years, and 71.50 (48–88) years in MVRp (p=0.75). In our study, 30 patients in MVRe and 32 in MVRp were females (46.9% and 50% respectively, p=0.72). The median weight was 79.50 (54–115) kg in MVRe and 77.50 (47–138) kg in MVRp (p=0.90).

Clinically 73.4% of patients in MVRe and 79.7% in MVRp were admitted with NYHA classification III/IV (p=0.36). EuroSCORE II was used to predict the mortality risk in our population in a standard fashion (13). The median EuroSCORE II in MVRe was 1.5% (0.56%–14.4%) and 1.67% (0.5%–25.43%) in MVRp (p=0.2).

25 in MVRe and 24 in MVRp (39.1% and 37.5% respectively, p=0.86) had non-requiring surgery coronary heart disease in their history. Previous myocardial infarction in patient history was observed in 3.1% of MVRe and 9.4% of MVRp (p=0.27). A history of atrial fibrillation has been documented in 46.9% of patients in MVRe and 51.6% in MVRp (p=0.6). One patient in each group had previous cardiac surgery, 2 patients in MVRe and 7 in MVRp had at least one stroke in their history (p=0.16).

Of the 22 patients with diabetes mellitus, 8 underwent repair and 14 underwent replacement (12.5% and 21.9% respectively, p=0.16). 49 patients with obesity (BMI [?] 30 kg/m^2) were identified, 22 underwent repair and 27 underwent replacement (34.4% and 42.2% respectively, p=0.36). Hypertension was observed in 105 patients, repair was performed in 51 (79.7%) patients and replacement in 54 (84.4%) patients (p=0.49) (Tab 2).

Preoperative Echocardiography findings:

A normal left ventricular ejection fraction ([?] 50%) was observed in 71,9% of patients in MVRe and 79,7% in MVRp (p=0.43). 31 (24.21%) patients underwent surgery with an impaired left ventricular function with a LVEF calculated at under 50%. A left atrial diameter [?] 50 mm was observed in 64.1% in MVRe and 56.3% in MVRp (p=0.37). A left ventricular end-diastolic diameter [?] 65mm was observed in 89.1% of MVRe and 95.3% of MVRp (p=0.19).

The Carpentier classification (Cc) was used in this study to identify MV pathology. In our study, 26 of 128 (20.3%) patients had a Cc type I. Of these, 20 underwent repair and six underwent replacement (31.3% vs. 9.4% respectively, p=0.002). Of the 67 (52.3%) patients who were admitted with Cc type II, 39 underwent repair versus 28 who underwent replacement (60.9% vs. 43.6% respectively, p=0.05). Of the 28 (21.9%) patients who presented with Cc type IIIa, two underwent repair and 26 underwent replacement (3.1% vs. 40.6%, p<0.001). Of the seven (5.5%) patients admitted with functional MVR (Cc type IIIb), three underwent repair and four underwent replacement (4.7% vs. 6.3% respectively, p=1.0).

Intraoperative findings:

In our study population, indication for surgery was elective in 72.7%, whereas surgery was urgent in 21.1% and emergent in 6.3% of patients. The aortic cross-clamp time, CBP time, and duration of surgery were not statistically significant in both groups (Tab 3)

30-day Outcome:

A reoperative procedure within 30 days was performed on two patients after repair with a diagnosis of systolic anterior motion (SAM) of mitral valve and chordae tendineae rupture. Both underwent a valve replacement on the 1st and 6thpostoperative day respectively. No reoperation was performed in the replacement group (p=0.5). We observed no major adverse cerebrovascular events and a single case of mesenteric ischemia in both groups.

Operative mortality was defined as death within 30 days after surgery or during the same hospitalization (14, 15). We observed no significant difference in 30-day mortality rates between the comparing groups. Two patients in MVRe and 5 patients in MVRp (3.1% versus 7.8%, p=0.44) passed away in the early hospital stay. Both patients in MVRe died due to postoperative cardiogenic shock and in MVRp one patient died with septic shock, one patient with mesenteric ischemia and the other patients demised with cardiogenic shock

Long-term Follow-Up:

During the follow-up period, we collected echocardiographic findings, performed on our study population within 3 years after surgery. They demonstrated 4 patients in MVRe and no patient in MVRp had severe MVR (2 patients with sole regurgitation and 2 patients with annular ring dislocation) within 3 years after surgery (p=0.09). A valve replacement was performed on one patient and the other 3 patients underwent valve re-repair; one patient is currently listed for heart transplant due to preoperatively known cardiomyopathy.

We observed altogether eight patients who required redo surgery within the follow-up period (Tab 4). A valve replacement was performed in five cases. Only one patient developed endocarditis after 6 months of MV replacement. This was treated operatively with a re-replacement.

Overall survival of the total population after 5 years was 85.1%. Survival in MVRe was 90.06% after 5 years and 79.54% in MVRp (p = 0.04) (Fig 1).

Predictors of short- and long-term Mortality:

As determined by the multivariate logistic regression model, patients with higher EuroSCORE II (1.24: OR 95%CI: 1.05–1.5, P=0.03), non-elective surgery (10.76: OR 95%CI: 1.25–230.66, P=0.05) or coronary artery disease (11.94: OR 95%CI: 1.49–285.92, P=0.04) were at high risk for 30 day-mortality (Fig 2).

According to the multivariate cox regression model we observed higher EuroSCORE II (1.14: HR 95% CI: 1.06–1.23, P<0.001), non-elective surgery (2.92: HR 95%CI: 1.11–7.68, P=0.03) or Smoking (3.02: HR 95%CI: 1.25–7.30, P=0.01) to be associated with a high risk of 5-year mortality (Fig 3).

Discussion:

The optimal surgical treatment for MVR remains under debate. The latest reports demonstrate MV repair is considered to be superior to replacement (7, 16). The excellent outcomes of surgical repair with a recommendation of risk stratification and earlier intervention when the probability of durable repair is high show low operative mortality and morbidity rates (2, 4, 7). In view of these findings, the rate of MV repair in Germany increased from 37.6% to 62.8% between 2000 and 2015 (17). These findings however remain debatable considering reports showing a benefit for preventing recurrence of MVR and rehospitalization with MV replacement. We decided to analyze our institutional results comparing repair and replacement using a propensity-matched analysis to homogenize the treatment groups and to perform a detailed statistical comparative analysis.

The age of a patient has long been considered an independent predictor of MV replacement (18). Silaschi et al. (19) showed patients who underwent MV repair were older compared to the replacement group. Thourani et al. (20) found that survival in the repair group was significantly higher than that in the replacement group in patients younger than 60 years, whereas this difference was not visible in patients older than 60. In our study, propensity-score matching was performed prior to analyze, with age being one of the baseline variables.

Vassileva et al (18) demonstrated that patients who had diabetes mellitus, myocardial infarction, stroke, previous cardiac surgery, and/or previous PCI in their history had a tendency to undergo replacement. In our study, the forementioned characteristics as well as the EuroSCORE II were similar between the two groups. In light of this, we believe that the decision against repair should not be based on the patient's age or history.

It is known that many factors are affecting the short and long-term outcomes of MV surgery. In our study, by performing a univariate logistic and multivariate regression analysis, we found that patients with CAD, or a history of it, had increased risk of in-hospital mortality. That could be due to reduced heart function as a result of the disease, and the acute side effects of CPB and cardioplegia which may cause an impairment in heart function in the first few hours after surgery, thus increasing the probability of developing low-cardiac output syndrome and the respective impact. Similar to Carino et al (13), our study showed that a high EuroSCORE II was associated with an increased 30-day mortality and higher adverse long-term outcomes. EuroSCORE II is widely considered an important predictor for 30-day mortality after cardiac surgery. It was validated in some studies in patients undergoing MV surgery (13, 21, 22) but we only found one study that explored the ability of EuroSCORE II to predict the 30-day mortality in patients undergoing MV surgery. They found that EuroSCORE II overestimates 30-day mortality (13).

Some surgeons believe MV repair is more complex, requiring longer X-clamp time and having a higher risk of recurrence (19). In our analysis, we observed that the difference between the two groups in CPB and X-clamp time were not statistically significant. These results were in agreement with the findings of Silaschi et al. (19) and Chivasso et al. (23), In contrast, Farid et al. (24) showed that patients who underwent repair have had shorter CPB and X-clamp times compared with those who underwent replacement. We know that cardiac and operative trauma can be reduced when CPB and X-clamp time are shorter, depending on the surgeon's experience.

In this study, we observed two cases of ring dehiscence requiring re-surgery. This complication after atrioventricular valves repair, particularly after MV repair, is not rare and is reported in 13–42% of procedural failures in MV annuloplasty repair (25). This complication led us to implement a modified approach by placing four pledgeted sutures on the A1, A3, P1 and P3 segments to reinforce the stability of the ring. Since using this strategy, we have not observed any new cases of ring dehiscence in our patients also those who not included in this trial.

The AATS Guidelines, AHA/ACC and ESC recommend repair to treat severe degenerative and ischemic MVR (2, 4, 26). The evidence for this recommendation is derived from single-center studies; however, the superiority of MV repair led the guidelines to consider the low probability of achieving a durable repair. This served as a reason to pass patients to specialized MV repair centers (2, 4). Some retrospective studies have reported some advantage of repair, in particular the operative mortality was lower compared to that of replacement (27-30). However, there is a multitude of studies showing no evidence for a preference of one intervention over the other (10, 16, 20, 28, 31).

This clinical investigation demonstrates that patients undergoing repair have similar mortality within 30 days after surgery, but lower mortality after 5 years compared with patients undergoing replacement.

Strengths:

The strong point of this study was that surgery was mainly performed by two surgeons, that reduces the operative bias. The strict implementation of rigid inclusion/exclusion criteria allowed for strong propensity-matching with similar preoperative patients' characteristics in both groups, leading to the credibility of short and long-term results.

Limitations:

The limitations of this study include the single-center nonrandomized study design and the limited number of patients. These may weaken the conclusions of the study.

Conclusions:

In patients with moderate to severe mitral valve regurgitation, repair can be performed with lower operative and 5-year mortality rates and is associated with better postoperative outcomes. Decision making for replacement vs. repair is influenced by the pathology of the valve. We agree that MV repair should be the treatment of choice for severe mitral regurgitation and should remain a central aspect in treatment algorithms and the quality measures of valve centers.

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Age Gender History of coronary heart disease History of atrial fibrillation History of stroke History of previous cardiac surg

Table 1: Propensity match characteristics

		Repair	Replacement	P value
Age (years)	Age (years)	70.5 (42-86)	71.5 (48-88)	0.75
female (n, %)	female (n, %)	30 (46.9%)	32 (50%)	0.72
Weight (kg)	Weight (kg)	79.5 (54-115)	77.5 (47-138)	0.90
Past History	Past History			
	Coronary heart disease (n, %)	25 (29.1%)	24 (37.5%)	0.86
	Atrial fibrillation (n, %)	30 (46.9%)	33 (51.6%)	0.60
	COPD[a] (n, %)	8 (12.5%)	16 (25%)	0.07
	Myocardial infarction (n, %)	2 (3.1%)	6 (9.4%)	0.27
	Previous cardiac surgery (n, %)	1 (1.6%)	1 (1.6 %)	1.00
	Stroke (n, %)	2 (3.1%)	7 (10.9%)	0.16
NYHA[b] classification	NYHA[b] classification			0.36

		Repair	Replacement	P value
	I	6 (9.4%)	8 (12.5%)	
	II	11 (17.2%)	5 (7.8%)	
	III	30 (46.9%)	36 (56.3%)	
	IV	17 (26.5%)	15 (23.4%)	
Risk factors	Risk factors			
	Diabetes mellitus (n, %)	8 (12.5%)	14 (21.9%)	0.16
	Hypertension (n, %)	51 (79.7%)	54 (84.4%)	0.49
	Obesity (n, %)	22 (34.4%)	27 (42.2%)	0.36
	Smoking (n, %)	13 (20.3%)	22 (34.4%)	0.07
	Hyperlipidaemia (n, %)	17 (26.5%)	24 (37.5%)	0.18

Table 2: Patients Characteristics:

[a]COPD: chronic obstructive pulmonary disease,[b]NYHA: New York Heart Association

		Repair	Replacement	P value
Indication of Surgery	Indication of Surgery			
	Elective (n, %)	50 (78.1%)	43 (67.2%)	0.17
	Urgent (n, %)	14 (21.9%)	13 (20.3%)	0.83
	Emergency (n, %)	0 (0%)	8 (12.5%)	0.006
CPB[a] time (min.)	CPB[a] time (min.)	90.5 (56-175)	99.5 (50-265)	0.10
X-Clamp time[b] (min)	X-Clamp time[b] (min)	58 (33-122)	66 (36-171)	0.13
Duration of surgery (min.)	Duration of surgery (min.)	166.5 (107-275)	178 (100-387)	0.41

Table 3: Intraoperative findings

[a]CPB: Cardiopulmonary bypass,[b]X-Clamp time: aortic cross-clamp time

Primary surgery	Cause of redo	Secondary Surgery	Time of redo after:
MVRp[a]	Endocarditis	Replacement	6 Months
	paravalvular leak	Replacement	2 Months
MVRe[b]	chordal rupture	Replacement	6 days
	SAM[c] Phenomena	Replacement	1 day
	Severe regurgitation	Replacement	3.5 years
		Repair	2 years
	Annular ring dehiscence	Repair	3 Months
		Repair	2.5 years

Table 4: Redo Surgery

[a]MVRp: mitral valve replacement,[b]MVRe: mitral valve repair, [c]SAM: systolic anterior motion

Figure Legends

Figure 1: Kaplan-Meier

Figure 2: Multivariate logistic Regression: 30 day-Mortality

Figure 3: Multivariate Cox Regression: 5 year-Mortality

Figure 4: Univariate Cox Regression: 5 year-Mortality

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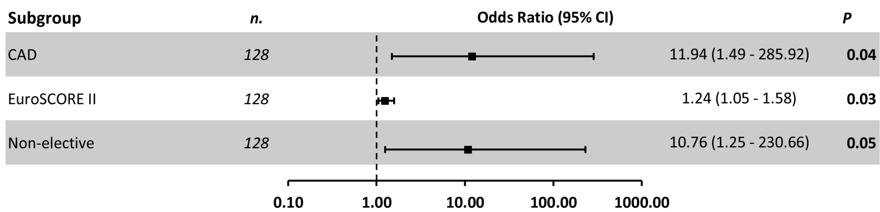

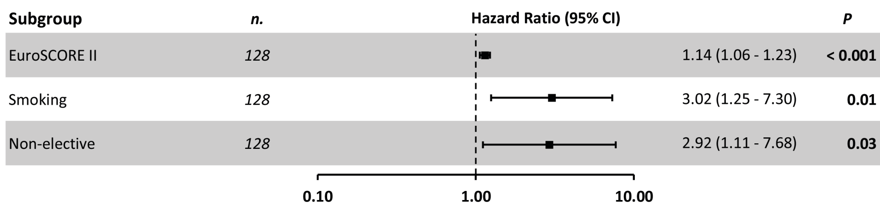

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