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0003-4975/$36.00
https://doi.org/10.1016/j.athoracsur.2023.08.032

Valve: Research

A Nationwide Study on Mitral Valve Repair vs Replacement for Active Endocarditis

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ABSTRACT

BACKGROUND Real-world evidence supporting the reproducibility and superiority of valve repair over replacement in active mitral valve infective endocarditis is lacking.

METHODS Data from a prospective nationwide database, including all cardiac surgical procedures in The Netherlands, were used. Adult patients undergoing primary mitral valve intervention who had a diagnosis of active infective endocarditis and who underwent surgery between 2013 and 2020 were included. Survival analysis was performed for the whole follow-up period as well as after applying the landmark of 90 days.

RESULTS Of 715 patients who met the inclusion criteria, 294 (41.1%) underwent valve repair. Mitral valve repair rates decreased slightly over the course of the study. The early mortality rate was 13.0%, and a trend of steadily declining early mortality rates over the course of the study, despite a steady increase in patient complexity, was observed. On risk-adjusted analysis, mitral valve replacement demonstrated inferior results when compared with valve repair (adjusted hazard ratio, 2.216; 95% CI, 1.425-3.448; $P < .001$), even after a landmark analysis was performed (adjusted hazard ratio 2.489; 95% CI, 1.124-5.516; $P = .025$). These results were confirmed by a propensity score–adjusted analysis (adjusted hazard ratio 2.251; 95% CI, 1.029-4.21; $P = .042$).

CONCLUSIONS Contemporary trends in mitral valve surgery for active infective endocarditis suggest growing patient complexity but slightly declining early mortality rates. A trend of decreasing mitral valve repair rates was seen. The results of this study suggest improved late outcomes of valve repair compared with valve replacement.

(Ann Thorac Surg 2024;117:120-7)

Mitral valve (MV) repair is preferred over valve replacement when a durable valve repair can be achieved. The superiority of valve repair is well documented in cases of degenerative MV disease, and it is currently the accepted treatment of choice for this disease type.[1] In other types of MV disease, however, the benefits of valve repair are less well established.

In active infective endocarditis, disease-specific characteristics have a significant effect on the outcome of surgery. The feasibility of valve repair is related to, among other factors, the volume of MV cases per year performed by a surgeon and center.[2] Moreover, technical considerations have an important effect on repair durability. In particular, many surgeons remain reluctant to perform prosthetic annuloplasty because of the presumed high risk of reinfection,[3,4] which could in turn significantly impair repair durability. Although the results from some specialized centers are encouraging and support the superiority of valve repair in this setting, the reproducibility of these results

The Supplemental Material can be viewed in the online version of this article [https://doi.org/10.1016/j.athoracsur.2023.08.032] on http://www.annalsthoracicsurgery.org.

Accepted for publication Aug 14, 2023.

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remains questionable.[5-7] A real-world analysis arguably provided new evidence to further support the use of valve repair in cases of infective endocarditis.[2] However, valve repair was feasible in only 18.6% of patients, and a survival benefit was present mostly in the early postoperative period and was less clear thereafter.

The aim of this study was to evaluate, in a nationwide study, the real-world outcomes of MV surgery in patients with active infective endocarditis. Moreover, we aimed to evaluate the clinical benefit of valve repair over valve replacement in this setting.

PATIENTS AND METHODS

SOURCE OF STUDY DATA. Data from the national database of the Netherlands Heart Registration were used for this study. The database is a mandatory prospective database of all cardiac surgical procedures performed in any of the 16 cardiothoracic surgery centers in the Netherlands. The basis for data collection was reported elsewhere.[8] The list of variables included in the database, as well as details on the completeness of data, are available online through the Netherlands Heart Registration.[9] Given the mandatory nature of data reporting, the proportion of missing data was very low (>99% complete). For all variables included, in short, the database contains a variety of data on all cardiac surgery procedures performed in The Netherlands. Collected in the data are patient demographic data, comorbidities (including all parameters included in the European System for Cardiac Operative Risk Evaluation [EuroSCORE] II risk calculator), intervention details, and outcomes. The outcomes include survival status and freedom from reintervention. Mortality data were derived from the municipal administration records and were almost complete for all patients (data were unavailable for 15 patients [2.1% of the total] who were lost to follow-up). MV reintervention was retrieved by cross-referencing the registry's database.

ETHICAL STATEMENT. This was a retrospective study of data extracted from the mandatory database of the Netherlands Heart Registration. Given the nature of the data source, no Institutional Review Board approval was needed. This study complied with the institution's ethical policies and standards.

INCLUSION CRITERIA. All adult patients (aged ≥18 years) who underwent MV surgery between 2013 and 2020 in any of the 16 cardiothoracic surgery centers in The Netherlands and who had a diagnosis of active infective endocarditis were eligible for study inclusion. No exclusion criteria regarding concomitant procedures performed were applied. Patients with a history of previous MV surgery were excluded, whereas a history of cardiac surgery of any other type did not result in exclusion. According to the database definition, any cases of healed infective endocarditis or other disease not including active endocarditis resulted in study exclusion.

STUDY END POINTS. The primary end points were overall survival (including survival during the whole follow-up duration and after the 90-day time point) and freedom from reintervention (defined as any surgical or transcatheter reintervention on the MV). Secondary end points included MV repair rate and early mortality (defined as, in accordance with the definition of the Netherlands Heart Registration database, mortality during the index hospitalization).

STATISTICAL ANALYSIS. Categoric data are displayed as counts and percentages. Continuous data are displayed as mean ± SD in cases of normally distributed data or median with interquartile range in cases where the data did not adhere to a normal distribution. The normality of distribution was assessed with the Kolmogorov-Smirnoff test. Intergroup comparison of categoric variables was made using the χ^2 test. For continuous data, an independent 2-tailed Student *t* test or Mann-Whitney *U* test was used if data were normally or nonnormally distributed, respectively.

Survival and freedom from reintervention rates were calculated and displayed using the Kaplan-Meier method. The log-rank test was used for intergroup comparison. For the whole study cohort, when comparing valve repair with valve replacement, Cox proportional hazards models at different time points were fitted to identify the risk factors for mortality as a function of time after the intervention. In addition to MV treatment modality, age, gender, previous cardiac surgery, critical preoperative state, insulin-dependent diabetes mellitus, poor mobility, aortic valve intervention, and tricuspid valve intervention were included as variables in the model. For each model, univariable and multivariable analyses were initially performed. All variables were then included in the multivariable model. Specifically, for each of the following periods, intervention to follow-up closure and 90 days after the intervention to follow-up closure (landmark analysis), we developed a separate Cox proportional hazards model to determine the risk factors related to event occurrence. The cutoff of 90 days was based on the clinical assumption that, in this complex patient group, the preoperative and perioperative factors influence the possibility of event occurrence (mortality) primarily during this period, whereas the influence of treatment modality (repair or replacement) is expected to affect event occurrence primarily in the later phase.[10] This approach was supported by graphic analysis of the Kaplan-Meier curves where the estimated hazard of

TABLE 1 Baseline Characteristics and Intraoperative Details

Characteristics	Mitral Valve Repair (n = 294)	Mitral Valve Replacement (n = 421)	*P* Value
Age, y	63.5 [53.0-70.0]	65.0 [55.0-73.0]	.028
Sex (female)	81 (27.6)	131 (31.1)	.30
Serum creatinine level, mg/dL	1.00 [0.82-1.28]	0.96 [0.77-1.35]	.67
Dialysis	5 (1.9)	10 (2.7)	.53
Previous cardiac surgery	71 (24.1)	45 (10.7)	<.001
Atrial fibrillation	38 (12.9)	56 (13.3)	.88
Insulin-dependent diabetes mellitus	13 (4.5)	34 (8.4)	.045
Chronic lung disease	22 (7.5)	32 (7.6)	.95
Extracardiac arteriopathy	18 (6.1)	40 (9.5)	.10
Critical preoperative state	28 (9.5)	82 (19.5)	<.001
History of stroke	46 (17.0)	82 (19.8)	.37
Recent myocardial infarction	8 (2.7)	16 (3.8)	.43
Poor mobility	15 (5.7)	55 (14.6)	<.001
Impaired left ventricular function	74 (25.2)	103 (24.7)	.89
EuroSCORE II	5.3 [2.6-15.9]	5.5 [2.9-13.6]	.59
Coronary artery bypass grafting	33 (11.2)	57 (13.5)	.36
Aortic valve operation	163 (55.4)	148 (35.2)	<.001
Tricuspid valve operation	34 (11.6)	26 (6.2)	.011
Cardiopulmonary bypass time, min	164 [114-223]	155 [118-213]	.70
Aortic cross-clamp time, min	119 [82-158]	109 [81-150]	.25

Data are presented as n (%) or median [interquartile range]. EuroSCORE, European System for Cardiac Operative Risk Evaluation.

event occurrence stabilized after 90 days after surgery for both groups.

Additionally, for each patient, a propensity score was calculated from a multivariable logistic regression model on preoperative characteristics (with same variables as included in the Cox proportional hazards regression model) as independent variables with valve repair vs replacement as a binary dependent variable. The weight was used as an independent variable in the multivariable Cox proportional hazards model for the analysis after applying the landmark of 90 days (weighted analysis). Subanalyses were performed for patients undergoing MV surgery without aortic valve surgery and for patients undergoing MV replacement with a biologic or mechanical prosthesis.

A P value of $<.05$ was considered statistically significant. Statistical analyses were performed with SPSS statistical software version 23.0 (IBM Corp).

RESULTS

A database search yielded 15,695 patients who underwent MV surgery in The Netherlands between 2013 and 2020; 715 of these 15,695 (4.6%) patients met the inclusion criteria and underwent either MV repair (n = 294; 41.1%) or MV replacement (n = 421; 58.9%). Of the patients undergoing valve replacement, 202 of 421 (48.0%) underwent biologic valve replacement, and 219 of 421 (52.0%) underwent mechanical valve replacement. Baseline characteristics of the whole patient cohort are presented in Table 1. Over the course of the study, the risk profile of operated patients increased. A clear increase in the proportion of patients undergoing operation in a critical preoperative state was observed. Moreover, the frequency of patients with impaired mobility increased, and patient age at the time of surgery slightly increased as well (Supplemental Figure 1).

When comparing the valve repair and replacement group, several differences in preoperative characteristics were observed. In general, patients who underwent valve repair were slightly younger and, interestingly, more often presented with a history of previous cardiac surgery. Patients in the valve replacement group more often presented in a critical preoperative state. Of note, the EuroSCORE II values were comparable between the groups.

EARLY RESULTS. Early mortality occurred in 93 patients, with an early mortality rate of 13.0% over the whole study period. The early mortality rate was 7.5% for the valve repair group and 16.9% for the valve replacement group ($P < .001$). Over the years, a decreasing trend in early mortality rate was observed, despite growing patient complexity, as reflected by a steady increase in the EuroSCORE II values over the years (Figure 1). Over the course of the study, a growing proportion of patients operated on were in a critical preoperative state (Supplemental Figure 1). Moreover, an increase in patient age at the time of surgery and a greater proportion of patients with mobility impairment were observed.

The repair rate decreased slightly over the years; the rate decreased from approximately 50% in the early years of the study to approximately 40% in the last years of the study (Figure 2). Conversely, the frequency of biologic MV replacement increased over the course of the study, with approximately one-third of patients undergoing bioprosthetic valve implantation in the early study years and approximately one-half in the last study years (Supplemental Figure 2).

OVERALL SURVIVAL AND FREEDOM FROM REINTERVENTION. During a mean follow-up period of 2.3 ± 1.7 years, 59 additional deaths occurred, 18 in the valve repair group and 43 in the valve replacement group. At 5 years after surgery, the overall survival rates were 81.7% (95% CI, 75.6%-87.8%) and 64.2% (95% CI, 56.7%-71.6%) in the valve repair and replacement groups ($P < .001$), respectively (Figure 3). In the whole study cohort, MV replacement was associated with significantly impaired survival when compared with valve repair (adjusted hazard ratio [HR], 2.216; 95% CI, 1.425-3.448; $P < .001$) (Table 2).

When a late phase analysis was applied (excluding patients who died within 90 days after surgery or whose follow-up was shorter than 90 days), MV replacement remained associated with impaired survival (adjusted HR, 2.489; 95% CI, 1.124-5.516; P = .025) (Table 3). Propensity score-adjusted Cox proportional hazards regression analysis revealed similar results (adjusted HR, 2.251; 95% CI, 1.029-4.21; P = .042).

At 5 years after surgery, the freedom from MV reintervention rates were 89.9% (95% CI, 74.4%-99.9%) in the valve repair group and 94.1% (95% CI, 86.8%-99.9%) in the valve replacement group (Supplemental Figure 3). No statistically significant difference in freedom from reintervention rates was observed (P = .69).

SUBGROUP ANALYSES. After excluding patients who underwent aortic valve procedure, 404 patients were left for subgroup analysis; 131 (32.4%) patients underwent valve repair, and 273 (67.6%) underwent valve replacement (Supplemental Table 1). At 5 years after surgery, the overall survival rates were 89.6% (95% CI, 83.1%-96.1%) and 67.7% (95% CI, 59.7%-75.7%) in the repair and replacement groups (P < .001), respectively (Supplemental Figure 4). The results were similar to the results of the whole study cohort, with MV repair providing outcomes superior to those with valve replacement on multivariable analysis (HR, 2.392; 95% CI, 1.166-4.905; P = .017) (Supplemental Table 2). When a landmark analysis was applied, only 23 events were left for analysis. On univariable analysis, MV repair demonstrated a nonsignificant trend to improved outcomes (HR, 2.399; 95% CI, 0.816-7.055; P = .11) (Supplemental Table 3). Given the lack of events of interest, no multivariable analysis was performed.

For patients undergoing MV replacement (Supplemental Table 4), no difference in overall survival was observed. At 5 years after surgery, the overall survival rates were 56.7% (95% CI, 40.0%-73.4%) for the biologic prosthesis group and 67.9% (95% CI, 59.5%-76.3%) for the mechanical prosthesis group (P = .28) (Supplemental Figure 5).

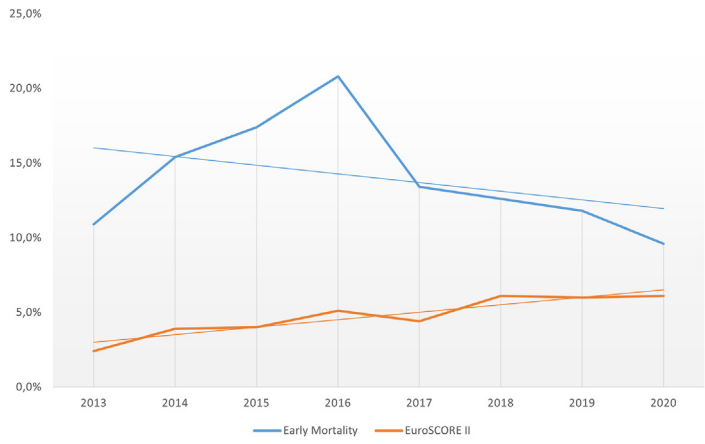

FIGURE 1 Preoperative European System for Cardiac Operative Risk Evaluation (EuroSCORE) II values increased steadily during the study period, reflecting increasing complexity of the operated cohort. Conversely, the early mortality rate decreased over the years.

COMMENT

The current study aimed to assess the contemporary trends in MV surgery for active infective endocarditis in a nationwide, multicenter registry. The data presented can be seen as real-world data, and several important observations and conclusions can be drawn. The early mortality rate after primary MV surgery for active infective endocarditis remains high. However, a trend of declining early mortality rates was observed, despite growing patient complexity. Moreover, the proportion of patients undergoing valve repair was satisfactory, but the frequency of valve repair seems to be decreasing. Late outcomes are superior for valve repair when compared with valve replacement.

Treatment of active infective endocarditis remains challenging and is made particularly difficult by the various comorbidities that patients usually present with, as well as by disease-specific complications. In the presence of a guideline-recommended indication for surgery, surgical intervention will improve clinical outcomes.[11,12] An ongoing infectious process and valvular tissue destruction with rapid evolution of valve dysfunction will often result in hemodynamic instability or septic clinical status. These characteristics were reflected in our study cohort as well because many patients presented with severe comorbidities, were in a critical preoperative state, or needed concomitant surgical procedures. The high EuroSCORE II values are a further reflection of these patient group-

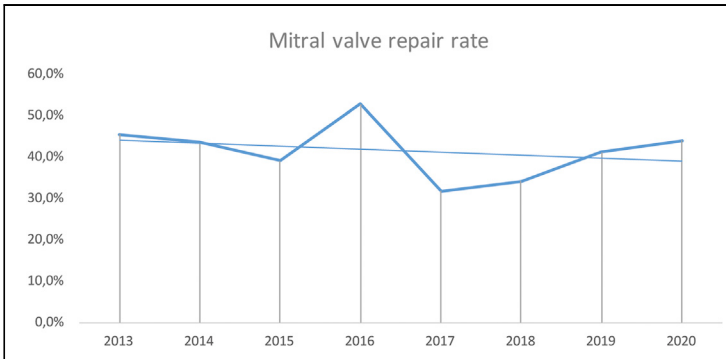

FIGURE 2 Over the study period, a trend of decreasing mitral valve repair rate was observed. The repair rate approached 50% at the beginning of the study period and declined to approximately 40% in the last years.

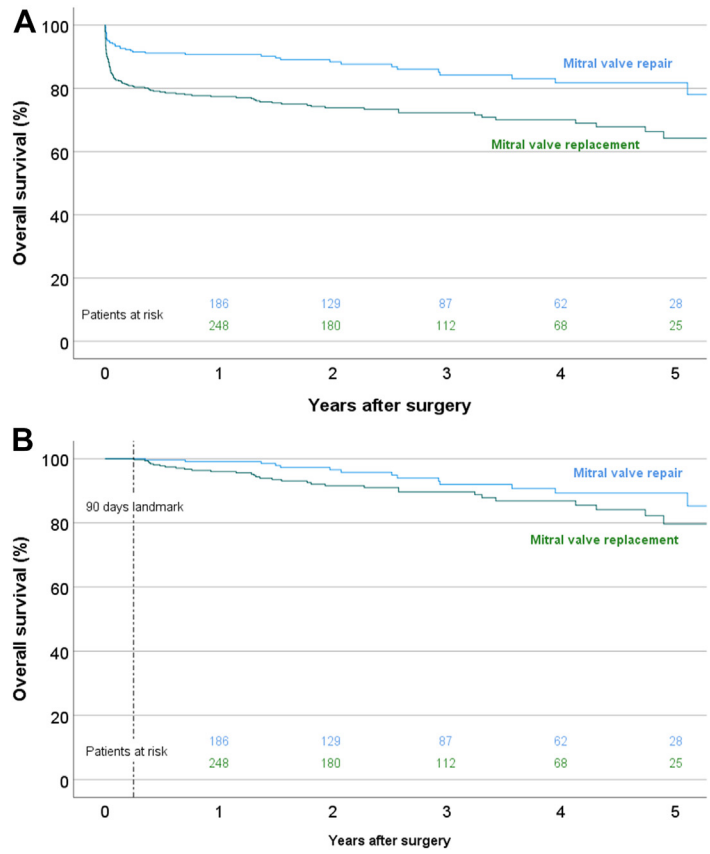

FIGURE 3 Overall survival rates for the mitral valve repair (blue line) and replacement (green line) groups. (A) Survival was better after valve repair, even when (B) a landmark analysis was performed.

related and disease-specific characteristics. Interestingly, the changes in patient profile suggest an adoption of a lower threshold for surgery in older patients with impaired mobility. Probably, surgical intervention was the only treatment possibility in these patients.

Early mortality occurred in 13.0% of the study population. These results are comparable to those noted in publications from a Spanish nationwide prospective registry and a multicenter report from the states of California and New York, reporting early mortality rates of 25.2% and 7.5%, respectively.[2,13] The early mortality rate in our study decreased gradually over the course of the study. Conversely, the risk profile of patients increased gradually, reflected by increasing EuroSCORE II values. This could be a result of increasing complexity of patients with infective endocarditis or a change in the threshold for surgery, with surgery currently performed in higher-risk patients as well. A similar increase in the risk profile of patients presenting with a first episode of infective endocarditis was observed in a retrospective cohort study from California and New York, including 75,829 patients.[14] To compensate for the early differences in patient mortality, likely unrelated to treatment allocation but related to patient characteristics and clinical status, a landmark analysis was performed. The analysis was performed to compensate for the time-related variability in the risk factors on outcome of interest and designed to address the question of late benefit of valve repair over replacement.

The rate of MV repair in active infective endocarditis varies considerably, and the reported repair rates range from 20% to 80%.[2,6,7,13,15] The highest repair rates have been reported by dedicated groups who have gathered extensive experience with treatment of infective endocarditis as well as reconstructive valve surgery in general. These results do not reflect real-world practice, and large differences exist among centers and countries. Valve repair is clearly not feasible in all patients, particularly when extensive valve destruction has already occurred.[16] Early diagnosis and treatment are crucial to prevent ongoing tissue destruction. We believe that the results presented in our study reflect not only surgical expertise but also the treatment of infective endocarditis in general. Even though repair is not feasible in all cases, many patients from the valve replacement group would likely have undergone valve repair if they had been treated in dedicated centers with high repair rates. Therefore, the observations

TABLE 2 Univariable and Multivariable Analysis on Overall Survival During Follow-up for the Whole Study Cohort

	Univariable Analysis			Multivariable Analysis		
Characteristics	**Hazard Ratio**	**95% CI**	***P* Value**	**Hazard Ratio**	**95% CI**	***P* Value**
Age, y	1.040	1.024-1.057	<.001	1.027	1.010-1.045	.002
Sex (female)	1.411	1.012-1.968	.043	1.333	0.911-1.951	.14
Previous cardiac surgery	1.983	1.372-2.868	<.001	1.770	1.109-2.823	.017
Insulin-dependent diabetes mellitus	2.215	1.352-3.632	.002	1.488	0.843-2.626	.17
Critical preoperative state	3.000	2.107-4.271	<.001	2.195	1.464-3.291	<.001
Poor mobility	1.954	1.233-3.099	.004	1.507	0.928-2.449	.19
Aortic valve operation	1.194	0.866-1.647	.28	1.311	0.877-1.959	.19
Tricuspid valve operation	0.754	0.384-1.479	.41	0.633	0.306-1.312	.22
Mitral valve replacement	2.264	1.561-3.283	<.001	2.216	1.425-3.448	<.001

TABLE 3 Univariable and Multivariable Analysis on Overall Survival During Follow-up After Applying the Landmark of 90 Days

	Univariable Analysis			Multivariable Analysis		
Characteristics	Hazard Ratio	95% CI	*P* Value	Hazard Ratio	95% CI	*P* Value
Age, y	1.023	0.997-1.050	.079	1.015	0.985-1.046	.32
Sex (female)	1.081	0.575-2.032	.81	1.113	0.516-2.403	.79
Previous cardiac surgery	1.114	0.497-2.496	.79	0.533	0.236-2.112	.71
Insulin-dependent diabetes mellitus	2.962	1.250-7.019	.014	2.124	0.722-6.247	.17
Critical preoperative state	1.135	0.447-2.877	.79	0.756	0.254-2.245	.61
Poor mobility	1.691	0.656-4.362	.28	1.658	0.614-4.479	.32
Aortic valve operation	1.281	0.714-2.298	.41	2.154	1.045-4.440	.037
Tricuspid valve operation	0.958	0.297-3.095	.94	0.994	0.295-3.352	.99
Mitral valve replacement	1.910	1.002-3.640	.049	2.489	1.124-5.516	.025

suggest the true clinical benefit of valve repair over valve replacement and may help guide future health care policies.

Technical considerations play a vital role in the feasibility and durability of MV repair in infective endocarditis. Annuloplasty seems to be performed often in expert centers with low early infective endocarditis recurrence rates.[5,6] Despite the use of additional prosthetic materials, additional risks are arguably negligible when radical resection is performed and proper antibiotic treatment is initiated.

Infective endocarditis remains a rather rare disease, with a reported incidence of approximately 10 cases per 100,000 persons.[14,17-19] Concentration of cases is challenging but important because single-surgeon case volumes and center case volumes affect treatment outcomes.[2] The repair rates seen in our study compare favorably with other multicenter real-world data, but a trend of decreasing repair rates is somehow concerning. This decrease is likely related to an increasing proportion of patients presenting in a critical preoperative state, thus suggesting that extensive valve destruction may have been present at the time of surgery.

The superiority of MV repair over valve replacement in infective endocarditis remains poorly established and accepted, even though some reports seem to support its use.[2,20,21] Particularly problematic is that after a reported early period of superiority of valve repair, late survival benefit is less clear. We performed a landmark analysis to tackle this issue. In the early postoperative period, extending to 90 days after surgery, the superiority of valve repair is to a lesser extent determined by treatment modality, whereas comorbidities and clinical status are likely to play a more important role. In an analysis including only patients who were still alive after the 90-day landmark, MV repair demonstrated a beneficial effect on overall survival. These results suggest that to improve late results, a structured approach, focused on early surgery and the use of extensive repair techniques that have demonstrated good repair durability, despite being technically challenging, could be applied. Previous studies support these observations because a beneficial effect of early surgery in left-sided infective endocarditis has readily been shown.[22-24]

STUDY LIMITATIONS. The study has several limitations inherent in the study design. The primary purpose of the Netherlands Heart Registration database consists of quality registration and control, with research purposes presenting only a secondary use. The low volume of patients treated per center during the course of the study presents the current standard of care in The Netherlands. Given the database restrictions, we were not able to analyze the effect of center and surgeon volume on repair rates and outcomes. The database lacks several treatment- and disease-specific variables (including details on repair techniques used and causative pathogens) that would be informative. Because of the lack of details on the amount of MV destruction at presentation, we cannot assess in which patients valve repair was feasible and in which patients valve destruction was already too severe to attempt valve repair. Moreover, given the database design, we could select only patients who underwent MV intervention in the presence of active infective endocarditis. The actual involvement of the MV in the infectious process cannot be guaranteed for all patients included in the study. We reason that the proportion of patients who may have undergone surgery without infection of the MV is negligible and does not limit the validity of our results. Moreover, although several characteristics of interest are lacking, the database allows assessment of the effect of treatment modality in a real-world setting, with analysis of the contemporary trends in patient care. The results therefore provide important guidance for further improvements in the treatment of patients with infective endocarditis.

CONCLUSION. Contemporary trends in MV surgery for active infective endocarditis suggest growing patient complexity but a slight decrease in early mortality

rates. A trend of decreasing valve repair rates was seen that is likely related to poor clinical status at presentation and growing patient complexity. Late treatment results of valve repair were superior to those of valve replacement.

FUNDING SOURCES

The authors have no funding sources to disclose.

DISCLOSURES

The authors have no conflicts of interest to disclose.

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0003-4975/$36.00
https://doi.org/10.1016/j.athoracsur.2023.08.034

Surgical Treatment of Active Mitral Valve Endocarditis

INVITED COMMENTARY:

In this issue of *The Annals of Thoracic Surgery*, Tomšič and colleagues[1] present a study on the surgical treatment of infective endocarditis of the mitral valve (MV) based on the national database of the Netherlands Heart Registration, a mandatory prospective database of all cardiac surgical procedures performed in any of the 16 units in the Netherlands. From 2013 to 2020, 715 patients had either MV repair