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Long-Term Outcomes of Sternal-Sparing Versus Sternotomy Approaches for Mitral Valve Repair: Meta-Analysis of Reconstructed Time-to-Event Data

Michel Pompeu Sá[1,2*], MD, MSc, MHBA, PhD, FACC, Xander Jacquemyn[3*], BSc, Ozgun Erten[2], MD, Jef Van den Eynde[3], BSc, Tulio Caldonazo[4], MD, Torsten Doenst[4], MD, PhD, Arjang Ruhparwar[5], MD, PhD, Alexander Weymann[5], MD, MHBA, PhD, FEBCTS, FESC, Rodrigo Oliveira Rosa Ribeiro de Souza[6], MD, Roberto Rodriguez[1,2], MD, FACC, FACS, Basel Ramlawi[1,2], MD, FRCSC, FACS, FACC, and Scott Goldman[1,2], MD

Abstract

Objective: Since there are concerns about the durability of mitral valve repair (MVRp) with minimally invasive techniques in patients with mitral regurgitation (MR), we aimed to evaluate the long-term outcomes of these sternal-sparing approaches when compared with conventional approaches with sternotomy in patients undergoing MVRp. **Methods:** We performed a systematic review according to a preestablished protocol and performed a pooled analysis of Kaplan–Meier–derived reconstructed time-to-event data from studies with longer follow-up comparing sternal-sparing versus sternotomy approaches for MVRp. Our outcomes of interest were survival, freedom from recurrent MR, and freedom from reoperation. **Results:** Eleven studies met our eligibility criteria comprising 7,596 patients with follow-up (sternal sparing, $n = 4{,}246$; sternotomy, $n = 3{,}350$). Patients who underwent sternal-sparing MVRp had a significantly lower risk of mortality over time compared with patients who underwent MVRp with sternotomy (hazard ratio [HR] = 0.29, 95% confidence interval [CI]: 0.23 to 0.36, $P < 0.001$) in the overall analysis. However, we found no statistically significant difference between the groups in the sensitivity analysis with adjusted populations (HR = 0.85, 95% CI: 0.63 to 1.15, $P = 0.301$). Regarding the outcomes freedom from recurrent MR and freedom from reoperation, we found no statistically significant differences between the groups in the follow-up in both overall and sensitivity analyses. **Conclusions:** In comparison with MVRp with sternotomy approaches, sternal-sparing MVRp was not associated with worse outcomes in terms of survival, recurrent MR, and reoperations over time.

Central Message

This meta-analysis of reconstructed time-to-event data included 11 studies. In comparison with mitral valve repair with sternotomy approaches, sternal-sparing mitral valve repair was not associated with worse outcomes in terms of survival, recurrent MR, and reoperations over time.

Keywords

mitral valve insufficiency, cardiovascular surgical procedures, cardiac surgical procedures, heart valves, meta-analysis

Introduction

The long-term benefits of sternal-sparing approaches for mitral valve repair (MVRp) in patients with mitral regurgitation (MR), when compared with conventional MVRp via sternotomy, are not well established.[1] Some authors have suggested faster recovery after surgery associated with shorter length of hospital stay.[2] Others have raised concerns about longer operative times, increased rates of complications (such as stroke), and inferior durability of the repair.[3]

A recent meta-analysis showed that sternal-sparing MVRp was not associated with worse outcomes in terms of operative mortality and complications despite longer operative times.[4] Nevertheless, the study identified an important lack of comparative studies with long-term results regarding the MVRp durability with both methods.

To fill this gap in the medical literature, we performed a pooled analysis of Kaplan–Meier–derived reconstructed time-to-event data to examine comparatively long-term outcomes of survival, freedom from reoperation, and freedom from recurrent MR between sternal-sparing and sternotomy approaches for MVRp.

Methods

Eligibility Criteria, Databases, and Search Strategy

This study followed the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) reporting guidelines.[5] Using the PICOS strategy (*P*opulation, *I*nterventions, *C*omparison, *O*utcome, and *S*tudy design), studies were included if the following criteria were fulfilled:

1. The population comprised patients who underwent surgical MVRp due to MR.
2. There was an intervention group undergoing sternal-sparing MVRp.
3. There was a second intervention group undergoing MVRp with sternotomy.
4. The outcomes studied included follow-up with survival/mortality rates, need for reoperation, or recurrent MR (with at least 1 of these outcomes accompanied by Kaplan–Meier curves).
5. The study design was retrospective or prospective, randomized or nonrandomized, monocentric or multicentric, and with matched or unmatched populations.

The following sources were searched for articles meeting our inclusion criteria and published by November 30, 2022: PubMed/MEDLINE, EMBASE, SciELO, LILACS, Cochrane Central Register of Controlled Trials (CENTRAL/CCTR), Google Scholar, and the reference lists of relevant articles. We searched using the following strategy: (Mitral Valve Prolapse OR Mitral Valve Insufficiency OR Mitral Valve Regurgitation OR Mitral Valve Incompetence OR Barlow syndrome OR Myxomatous valvular disease) AND (Mitral Valve Repair OR Mitral Valve Annuloplasty) AND (Minimally Invasive Surgical Procedures OR Thoracotomy OR Video-Assisted Surgery OR Robotic-Assisted Surgery).

The following steps were taken for study selection: (1) identification of titles of records through database search, (2) removal of duplicates, (3) screening and selection of abstracts, (4) assessment for eligibility through full-text articles, and (5) final inclusion in study. Studies were selected by 2 independent reviewers. When there was disagreement, a third reviewer made the decision to include or exclude the study. Ethical approval was not applicable for this study, as it consisted of a systematic review and meta-analysis. There were no language restrictions.

Risk of Bias Assessment

The Risk of Bias in Non-Randomized Studies of Interventions tool (ROBINS-I) was systematically used to assess the included studies for risk of bias.[6] The studies and their characteristics were classified into low, moderate, and serious risk of bias. Two independent reviewers assessed risk for bias. When there was a disagreement, a third reviewer checked the data and made the final decision.

Statistical Analysis

We used the "curve approach," which reconstructs individual patient data (IPD) based on the published Kaplan–Meier graphs from the included studies.[7,8] In this meta-analysis, we used the two-stage approach as described by Liu et al. based on the R package "IPDfromKM" (version 0.1.10).[9] In the first stage, raw data coordinates (time, survival probability) were extracted from each treatment arm in each of the Kaplan–Meier curves. In the second stage, the data coordinates were processed based on the raw data coordinates from the first stage in conjunction with the numbers at risk at given time points, and IPD were reconstructed.

Finally, the reconstructed IPD from all studies were merged to create the study dataset. The cumulative incidence of all-cause mortality at follow-up in both treatment arms (aggressive and conservative) was visually assessed using Kaplan–Meier estimates with the R packages "survival" (version 3.2-13) and "survminer" (version 0.4.9). Hazard ratios (HRs) with 95% confidence intervals (CIs) for the difference between the 2 treatment arms were calculated using a Cox regression model with the R package "coxphw" (version 4.0.2). The proportionality of

[1]Department of Cardiothoracic Surgery, Lankenau Heart Institute, Lankenau Medical Center, Main Line Health, Wynnewood, PA, USA
[2]Department of Cardiothoracic Surgery Research, Lankenau Institute for Medical Research, Wynnewood, PA, USA
[3]Department of Cardiovascular Sciences, KU Leuven, Belgium
[4]Department of Cardiothoracic Surgery, Friedrich-Schiller-University Jena, Germany
[5]Department of Cardiothoracic, Transplantation and Vascular Surgery, Hannover Medical School, Medizinische Hochschule Hannover (MHH), Germany
[6]Department of Cardiothoracic Surgery, University of South Florida, USF Health, Tampa, FL, USA

*These authors contributed equally to this work.

Corresponding Author:
Michel Pompeu Sá, MD, MSc, MHBA, PhD, FACC, Lankenau Institute for Medical Research, Lankenau Heart Institute, Main Line Health, 100 East Lancaster Avenue, Suite 215, Wynnewood, PA 19096 USA.
Email: michel_pompeu@yahoo.com.br

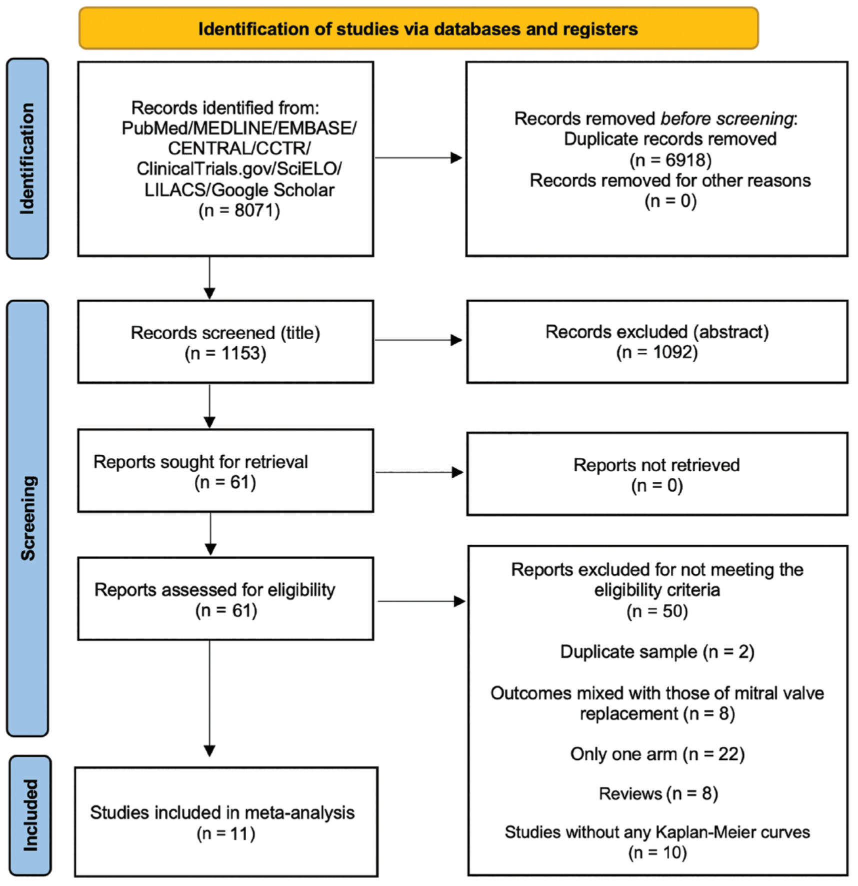

Fig. 1. Flow diagram of studies included in data search. Flowchart according to the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) reporting statement.

the hazards of the Cox model was checked with the Grambsch–Therneau test and diagnostic plots based on Schoenfeld residuals.[10] Our protocol stated that flexible parametric survival models with B-splines and landmark analysis would be performed in case the proportional hazards assumption was violated, as apparent either from these tests or from visual inspection of the Kaplan–Meier curves.

Much like Cox regression models, flexible parametric survival models (also known as Royston–Parmar models or generalized survival models) with B-splines provide HRs with 95% CIs as a measure of association between exposures and outcome, with the addition that they allow the time effect(s) to be smooth.[11,12] As a result, they do not depend on proportional hazards and can capture a wide range of hazard shapes. In the present study, we modeled the baseline hazard rate based on a spline with 4 degrees of freedom (3 intermediate knots and 2 knots at each boundary, placed at quartiles of distribution of events), using the R package "rstpm2" (version 1.5.2). Interactions between treatment arm and time were added to the model using a second spline function. The resulting output estimates time-varying HRs with 95% CIs for every given time point during follow-up. For studies reporting interquartile ranges for characteristics of patients and/or procedures, the mean was estimated using a validated formula.[13]

All analyses were completed with R Statistical Software version 4.1.1 (Foundation for Statistical Computing, Vienna, Austria).

Results

Study Selection and Patient Characteristics

After excluding duplicates and ineligible studies, 11 studies met our eligibility criteria (Fig. 1).[14–24] Only 1 study was randomized, and 2 studies were multicentric and prospective. The Supplemental Tables present the study characteristics, patient characteristics, baseline New York Heart Association functional status, underlying mitral valve pathology, surgical techniques applied during the procedure, and types of cannulations during sternal-sparing MVRp. The overall population comprised 7,596 patients with follow-up (sternal sparing, n = 4,246; sternotomy, n = 3,350). The mean age ranged from 40 to 68.5 years, and 9 studies (81.8%) had populations with a mean age less than 60 years. The overall population was mostly

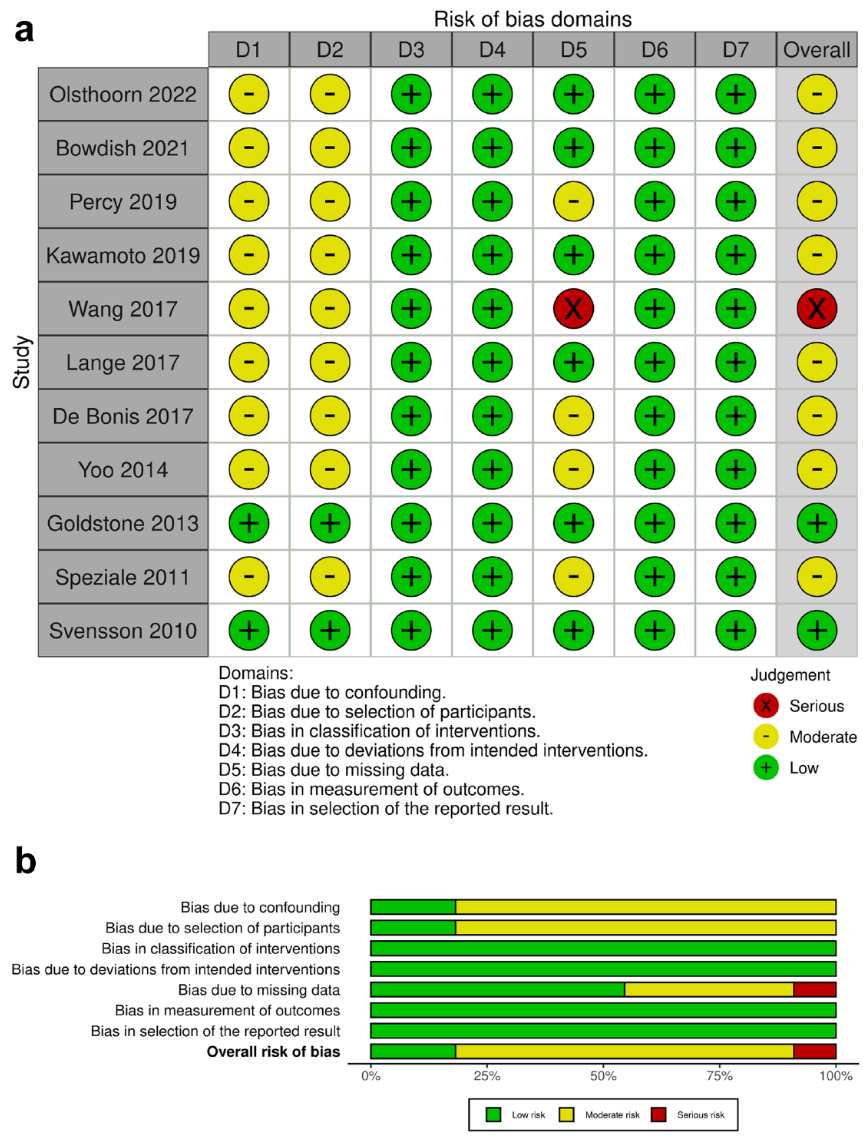

Fig. 2. Risk of bias summary. The Risk of Bias in Non-Randomized Studies of Interventions (ROBINS-I) tool with (a) traffic lights and (b) summary plots.

composed of patients with degenerative, myxomatous, or Barlow disease, whereas other etiologies such as functional, ischemic, or rheumatic disease had very low representation. Most sternal-sparing approaches consisted of minithoracotomy performed through the third or fourth intercostal space with peripheral cannulation through the femoral vessels. Figure 2 shows the qualitative assessment of the studies with the ROBINS-I tool, and we identified an overall moderate risk of bias, at least.

Long-Term Outcomes: Overall Population

Figure 3 depicts the pooled Kaplan–Meier curves for survival (Fig. 3a), freedom from recurrent moderate or severe MR (Fig. 3b), and freedom from reoperation (Fig. 3c).

To conduct the analysis for survival (Fig. 3a), the data of 6,233 patients (sternal sparing, n = 3,552; sternotomy, n = 2,681) from 9 studies were pooled. Patients who underwent sternal-sparing MVRp had a significantly lower risk of mortality compared with patients who underwent MVRp with sternotomy (HR = 0.29, 95% CI: 0.23 to 0.36, $P < 0.001$).

For the analysis of cumulative risk of recurrent MR (Fig. 3b), the data of 911 patients (sternal sparing, n = 549; sternotomy, n = 362) from 4 studies were pooled. Patients who underwent sternal-sparing MVRp did not present a statistically significant difference in comparison with patients who underwent MVRp with sternotomy (HR = 0.78, 95% CI: 0.48 to 1.27, $P = 0.316$) for this outcome.

For the analysis of cumulative risk of reoperation (Fig. 3c), the data of 3,563 patients (sternal sparing, n = 1,646;

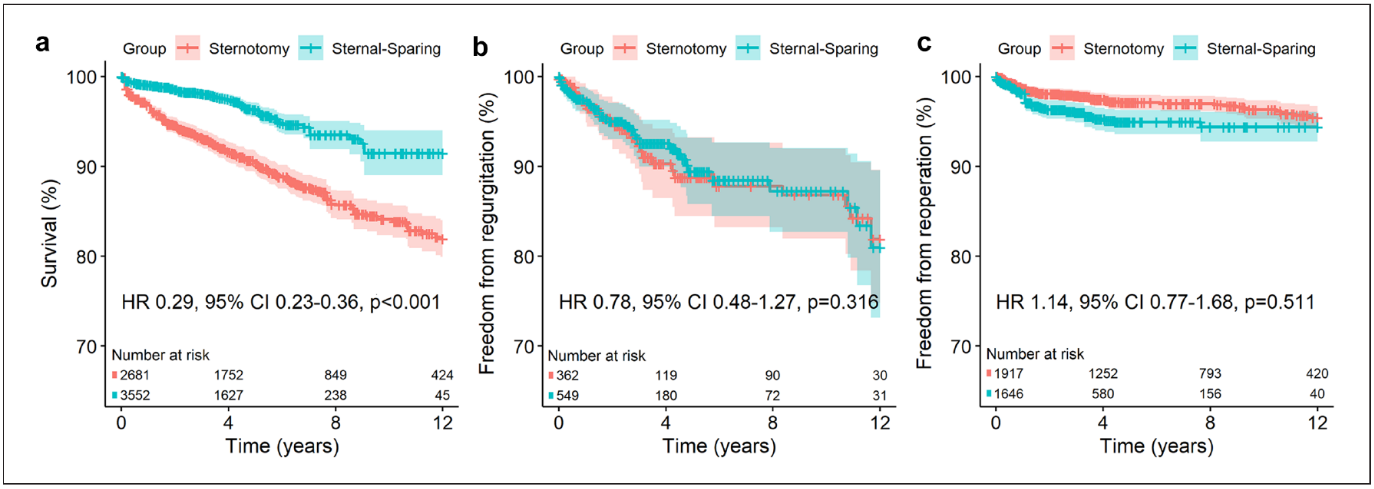

Fig. 3. Pooled Kaplan–Meier curves for the overall population showing (a) survival, (b) freedom from recurrent mitral regurgitation, and (c) need for reoperation in patients who underwent mitral valve repair with sternal-sparing versus sternotomy approaches. The pooled Kaplan–Meier curves are accompanied by their respective time-varying HR with 95% CI at every given time during follow-up, which are derived from flexible parametric survival models with B-splines. CI, confidence interval; HR, hazard ratio.

sternotomy, n = 1,917) from 7 studies were pooled. Patients who underwent sternal-sparing MVRp did not present a statistically significant difference in comparison with patients who underwent MVRp with sternotomy (HR = 1.14, 95% CI: 0.77 to 1.68, P = 0.511) for this outcome.

Sensitivity Analysis

To pool data from more balanced populations (in terms of their baseline characteristics), we carried out sensitivity analyses including only Kaplan–Meier curves of populations from randomized controlled trials, propensity score–matched studies, and inverse probability of treatment weighting analyses, leaving out those Kaplan–Meier curves with unweighted or unadjusted analyses. Figure 4 depicts the pooled Kaplan–Meier curves for survival (Fig. 4a), freedom from recurrent moderate or severe MR (Fig. 4b), and freedom from reoperation (Fig. 4c).

To conduct the analysis for survival (Fig. 4a), the data of 3,127 patients (sternal sparing, n = 1,254; sternotomy, n = 1,873) from 7 studies were pooled. Patients who underwent sternal-sparing MVRp did not present a statistically significant difference in comparison with patients who underwent MVRp with sternotomy (HR = 0.85, 95% CI: 0.63 to 1.15, P = 0.301) for this outcome.

For the analysis of cumulative risk of recurrent MR (Fig. 4b), the data of 634 patients (sternal sparing, n = 347; sternotomy, n = 287) from 3 studies were pooled. Patients who underwent sternal-sparing MVRp did not present a statistically significant difference in comparison with patients who underwent MVRp with sternotomy (HR = 0.90, 95% CI: 0.50 to 1.61, P = 0.728) for this outcome.

For the analysis of cumulative risk of reoperation (Fig. 4c), the data of 586 patients (sternal sparing, n = 293; sternotomy, n = 293) from 3 studies were pooled. Patients who underwent sternal-sparing MVRp did not present a statistically significant difference in comparison with patients who underwent MVRp with sternotomy (HR = 1.65, 95% CI: 0.68 to 4.04, P = 0.270) for this outcome.

Discussion

Summary of Evidence

To the best our knowledge, this study is the first pooled meta-analysis of reconstructed time-to-event data comparing long-term outcomes of sternal-sparing versus sternotomy approaches for MVRp in patients with MR. Our study revealed that, in the long run, MVRp with sternal-sparing approaches offers at least similar outcomes in comparison with MVRp with sternotomy approaches.

Comments

Because little is known about the long-term results of sternal-sparing approaches for MVRp in head-to-head comparisons with sternotomy approaches, some surgeons raise valid concerns as to whether we might be paying a price to operate in a minimally invasive fashion by compromising the long-term results of MVRp, whose ultimate goals should remain low postoperative mortality, a low incidence of recurrent moderate or severe MR, and a very low incidence of valve-related reoperation in the long term. The reasons for these concerns would be poor visualization of surgical field with ensuing inappropriate evaluation of the mitral valve and difficulty with mobilization of surgical instruments in a limited space. However, according to the results of our study, these concerns might be unfounded.

Another aspect that concerns surgeons is related to availability of personnel, facilities, and procedural costs. Grossi et al., on behalf of the Economic Workgroup on Valvular

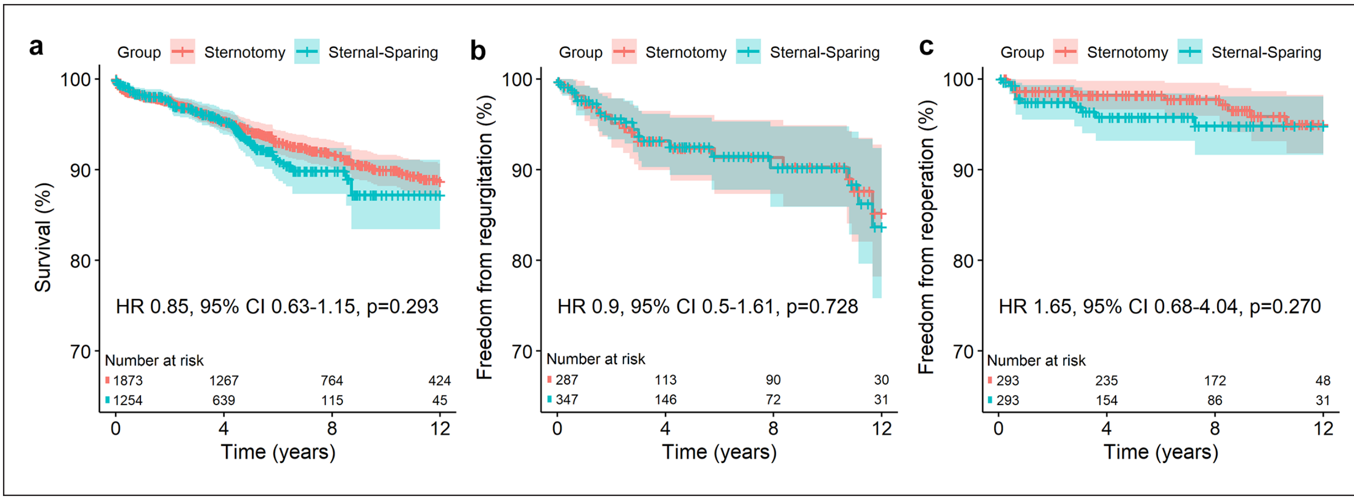

Fig. 4. Pooled Kaplan–Meier curves for adjusted populations showing (a) survival, (b) freedom from recurrent mitral regurgitation, and (c) need for reoperation in patients who underwent mitral valve repair with sternal-sparing versus sternotomy approaches. The pooled Kaplan–Meier curves are accompanied by their respective time-varying HR with 95% CI at every given time during follow-up, which are derived from flexible parametric survival models with B-splines. CI, confidence interval; HR, hazard ratio.

Surgery of the United States, demonstrated that minimally invasive cardiac surgery (MICS) was associated with a reduction in the mean hospitalization cost of US$8,289 (17.2% reduction in costs) among more than 600 hospitals participating in their database.[25] Some factors contributing to these savings was a 2-day reduction in hospital stay associated with MICS (mean cost, US$1,122 for MICS vs US$1,671 for sternotomy) and blood use was significantly reduced with MICS. Grossi et al. also observed that sternal-sparing approaches were more likely than sternotomy approaches in teaching hospitals (64% vs 36%, $P < 0.001$) and hospitals with more than 600 beds (78% vs 22%, $P < 0.001$).[25] One might hypothesize that larger hospitals have funds and personnel enough to support MICS. Teaching hospitals, being those where specialized personnel are trained and cutting-edge surgical science is ubiquitous, are expected to go for more innovative techniques and push the bounds of new technologies in MICS.

Unfortunately, we did not find any studies with head-to-head comparisons between robot-assisted MVRp versus conventional approaches with sternotomy. However, due to the current upward trend in the use of robotic platforms in this scenario, we believe this topic deserves to be addressed. A recent meta-analysis including 9 studies and 3,300 patients undergoing robotic MVRp revealed that the rates of overall survival at 1, 5, and 10 years were 99.2%, 97.4%, and 92.3%, respectively.[26] Freedom from mitral valve reoperation at 8 years after robotic MVRp was 95.0%. Freedom from moderate or severe recurrent MR at 7 years was 86.0%. Although these results are promising, we still need future head-to-head comparisons between MVRp procedures carried out with sternotomy and with nonrobotic minithoracotomy approaches to clarify whether the robotic platforms add some value to the treatment delivery without losing quality of immediate and long-term outcomes.

Although not part of the scope of our work, we believe it is worth mentioning the importance of multicentric follow-up specific for MR recurrence and ensuing reoperation due to differences between institutions and surgeons with different case volumes. For example, a study carried out in the state of New York including a total of 313 surgeons from 41 institutions observed a significant association between low surgeon volume and increased risk of mitral valve reoperation within 12 months of follow-up after MVRp ($P = 0.04$).[27] The cumulative incidence of reoperation at 12 months was 1.3% (95% CI: 1.0% to 1.8%) for patients operated on by a surgeon with a total annual surgeon volume of ≥25 operations as compared with 3.6% (95% CI: 2.4% to 5.0%) for patients operated on by a surgeon with a total annual surgeon volume of <25 operations ($P = 0.003$). The significant difference in reoperation rates persisted to 12 years ($P < 0.001$). This study illustrates the importance of monitoring results over time to measure quality.

Limitations

As in any systematic review with meta-analysis, the possible biases in the original studies such as the nonmulticentric, retrospective, and single-center nature can have an impact on the pooled results. Furthermore, this study is focused on the delivery of treatment (minimally invasive vs conventional approaches) instead of the treatment itself (annuloplasty, edge-to-edge-repair, resection of leaflets, implantation of neochords, etc.), and the surgical technique applied may have influenced our findings. Besides, the vast majority of the populations included in our study were composed of patients with myxomatous, degenerative, or Barlow disease, and we should be cautious about extrapolating the validity of these results to functional, ischemic, or rheumatic patients who were underrepresented in the pooled population. Considering that we do not know to what degree the cases were selected based on unreported criteria, we should also include here the likely selection bias in favor of healthier or less complex patients for sternal-sparing MVRp.

An aspect not captured by our study is whether there were significant differences between the groups in terms of coaptation length after MVRp, which has been considered an independent predictor of recurrent MR in patients with functional and degenerative MR.[28]

Furthermore, we should bear in mind that the pooled data come from experienced centers, and we examined reported outcomes without granular knowledge of nonstandard preoperative assessment employed to select candidates.

Conclusions

In comparison with MVRp with sternotomy approaches, sternal-sparing MVRp was not associated with worse outcomes in terms of survival, recurrent MR, and reoperations over time.

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Declaration of Conflicting Interests

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ORCID iDs

Michel Pompeu Sá https://orcid.org/0000-0001-5356-2996
Xander Jacquemyn https://orcid.org/0000-0001-8421-0686

Supplemental Material

Supplemental material for this article is available online.

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