Tricuspid valve annuloplasty and mitral valve replacement are associated with bradyarrhythmia after mitral valve surgery

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Abstract
Introduction: Mitral valve surgery has developed into a strong subspecialty of cardiac surgery with operative techniques and outcomes constantly improving. The development of bradyarrhythmias after mitral valve surgery is not completely understood.

Methods: We investigated a cohort of 797 patients requiring mitral valve surgery with and without concomitant procedures. Incidences and predictors of pacemaker requirement as well as survival were analyzed.

Results: In the complete follow-up period (median follow-up time: 6.09 years [95% confidence interval [CI]: 5.94–6.22 years, maximum 8.77 years] 80 patients (10% of the complete cohort) required pacemaker implantation for bradyarrhythmia. The cumulative rate of pacemaker implantation was 6.4% at 50 days (48 patients) with most (54.2%) requiring pacing for atrioventricular block. Mitral valve replacement (odds ratio [OR]: 1.905; 95% CI: 1.206–3.536; p = .041) and tricuspid ring annuloplasty (OR: 2.348; 95% CI: 1.165–4.730, p = .017) were identified as operative risk factors of pacemaker requirement after mitral valve surgery. Insulin-dependent diabetes mellitus was also identified as a predictor of pacemaker requirement (OR: 4.665; 95% CI: 1.975–11.02; p = .001). There was no difference in survival in the paced and unpaced groups.

Conclusions: After mitral valve surgery, a relevant subgroup of patients requires pacemaker implantation—most for atrioventricular block. We identified mitral valve replacement and tricuspid ring annuloplasty as significant operative risk factors and insulin-dependent diabetes mellitus as a demographic risk factor. While anatomic relationships help explain the operative risk factors the role of diabetes mellitus is not completely understood.

Keywords
atrioventricular block, bradyarrhythmia, mitral valve surgery, pacemaker implantation, tricuspid valve annuloplasty
1 | INTRODUCTION

Mitral valve surgery has gained a strong foothold in the treatment of mitral valve disease in the last five decades. This subspecialty has evolved consistently with the development of new surgical techniques for valve repair and a shift toward novel surgical access routes. The extent of surgery performed can span from correction of prolapse of an isolated scallop to complex repair or replacement in bileaflet disease. Furthermore, mitral valve surgery can be associated with multiple concomitant procedures such as tricuspid valve repair, surgical ablation for atrial fibrillation, and coronary artery bypass grafting. While decades ago mitral valve replacement was commonplace current recommendations emphasize the importance of grafting. While decades ago mitral valve replacement was commonly performed to reduce the rate of pacemaker requirement in this patient group. With our study, we sought to provide a detailed investigation of pacemaker implantation rates from a cohort of all patients requiring mitral valve surgery as to be able to purvey widely applicable conclusions. Ideally, we hoped to identify factors which can be influenced as to reduce the rate of pacemaker requirement in this patient group.

2 | METHODS

2.1 | Study type and cohort

The study presented herein represents a retrospective cohort study investigating all patients receiving any form of mitral valve surgery (with any form of concomitant procedure) at our institution between the years 2011 and 2014. This timeframe for the mitral valve procedure was chosen to allow for an adequate number of patients and an adequate follow-up time at the time of investigation. Patients with an age under 18 years and patients who already had received a permanent pacemaker before mitral valve surgery were excluded. The study was approved by the local ethics committee.

2.2 | Groups and definitions

Patients who required pacemaker implantation within 50 days of surgery were allocated to the permanent pacemaker group (PPM); all other patients were designated to the no permanent pacemaker group (No PPM). Glomerular filtration rate (GFR) was calculated using the Chronic Kidney Disease Epidemiology Foundation formula (CKD-EPI) based on serum creatinine levels.

2.3 | Statistics

For the identification of predictors of permanent pacemaker implantation after surgery, the PPM group was compared with the No PPM group. All data were analyzed using R Version 3.5.0 using the software package survival. Statistical analysis of categorical data was performed using Fisher’s Exact Test with results shown as odds ratios (OR) with associated 95% confidence intervals (CI). Scale data were evaluated using the Wilcoxon–Mann–Whitney test and are presented as medians with the associated interquartile ranges. Select variables found to be significant predictors in univariable testing were evaluated with multivariable testing (binary logistic regression). Variables identified via multivariable testing were considered relevant predictors. Time to event data (time to death or time to pacemaker implantation) were evaluated using the Kaplan-Meier method. For the survival statistic all data with death or loss to follow-up within 50 days of surgery was excluded from analysis. The median follow-up time was calculated using the reverse Kaplan-Meier method.

3 | RESULTS

3.1 | Baseline characteristics of the cohort

See Table 1 for the baseline characteristics of the patients in our mitral valve surgery cohort.

3.2 | Pacemaker implantation rates and indications

In our study with a median follow-up time of 6.09 years (95% CI: 5.94–6.22) and a maximum follow-up time of 8.77 years a total of 80 patients (10.0%) required a pacemaker for bradycardic rhythm disturbances. The cumulative rate of pacemaker implantation (calculated with the Kaplan-Meier estimator—taking patient death into account) was 3.9% (95% CI: 2.5–5.3) at 10 days, 6.1% (95% CI: 4.4–7.8) at 30 days, 6.4% (95% CI: 4.6–8.1) at 50 days, 7.8% (95% CI: 5.9–9.8) at 1 year and 12.1% (95% CI: 9.4–14.7) at 8 years. The change in cumulative rate of implantation over time is depicted in Figure 1.

Of the 48 patients requiring a pacemaker within 50 days of surgery (the patients investigated herein) 26 (54.2%; 3.26% of the complete cohort) required a pacemaker due to atrioventricular block (AVB), 15 (31.2%; 1.88% of the complete cohort) required a pacemaker due to sinus node dysfunction and 7 (14.6%; 0.88% of the...
complete cohort) required a pacemaker due to atrial fibrillation with a slow ventricular rate.

### 3.3 | Predictors of pacemaker implantation

Predictors of pacemaker implantation within the first 50 days after surgery were investigated via univariable analysis and are presented in Figure 2. Scale predictors (age, GFR, Euroscore II, and operative times) are presented as scatter plots in Figure 3.

As can be gathered from Figure 2 mitral valve replacement was found to be associated with a higher risk of pacemaker implantation. Mitral valve prolapse was found to be associated with a decreased risk. Mitral valve prolapse was associated with a lower risk of mitral valve replacement (OR: 0.188; 95% CI: 0.137–0.257; p < .001).

Tricuspid valve ring annuloplasty was also found to be associated with postoperative pacemaker requirement. To test for confounding the association between the type of mitral valve procedure and tricuspid valve ring annuloplasty were investigated. Mitral valve replacement was not associated with a higher rate of tricuspid valve ring annuloplasty (OR: 1.105; 95% CI: 0.717–1.703; p = .676).

Diabetes mellitus and especially insulin-dependent diabetes mellitus were found to be associated with a higher risk of pacemaker implantation. Both were also associated with higher rates of coronary artery disease (OR: 2.24, 95% CI: 1.45–3.48, p < .001 (for diabetes mellitus)) and coronary artery bypass grafting (OR: 3.23, 95% CI: 1.52–6.73, p = .001 (for diabetes mellitus)) being performed as a concomitant procedure.

The results of multivariable investigation of predictors are presented in Table 2.

### 3.4 | Comparison of survival in patients requiring and not requiring pacemaker implantation

Survival in the PPM and No PPM groups is depicted in the Kaplan–Meier graph labeled Figure 4. Data presented includes only patients which survived a minimum of 50 days. No significant difference was found between the survival in the PPM and No PPM groups (p value of log-rank test [Mantel–Cox]: 0.063). Pacemaker implantation was associated with a hazard ratio of 1.824 (95% CI: 0.786–4.23) for mortality.

### Table 1 Baseline characteristics of the mitral valve surgery cohort comparing the patients requiring pacemaker implantation postoperatively with those not requiring pacemaker implantation

| Variable                  | No PPM (%/IQR) | PPM (%/IQR) | p Value |
|---------------------------|----------------|-------------|---------|
| Complete patient group    | 749 (94.0)     | 48 (6.0)    |         |
| Age (years)               | 70 (60–76)     | 72 (69–76)  | .087    |
| Gender, female            | 310 (41.4)     | 23 (47.9)   | .374    |
| COPD                      | 72 (9.7)       | 5 (10.4)    | .802    |
| Diabetes                  |               |             | .001    |
| IDDM                      | 28 (3.7)       | 8 (16.7)    |         |
| NIDDM                     | 64 (8.5)       | 4 (8.3)     |         |
| LVEF (%)                  | 62 (53–70)     | 57 (51–69)  | .340    |
| NYHA                      |               |             | .286    |
| IV                        | 114 (15.6)     | 9 (18.8)    |         |
| III                       | 394 (53.8)     | 28 (58.3)   |         |
| II                        | 107 (14.6)     | 8 (16.7)    |         |
| I                         | 118 (16.1)     | 3 (6.3)     |         |
| Active endocarditis       | 87 (11.6)      | 5 (10.4)    | .801    |
| Mitral valve disease      |               |             | .155    |
| Mitral valve regurgitation| 656 (87.6)     | 38 (79.2)   |         |
| Mitral valve stenosis     | 18 (2.4)       | 3 (6.3)     |         |
| Combined disease          | 71 (9.5)       | 7 (14.6)    |         |
| Mitral valve prolapse     | 365 (48.9)     | 15 (31.3)   | .024    |
| Etiology of mitral valve disease |           |             | .686    |
| Degenerative              | 509 (68.0)     | 32 (66.7)   |         |
| Ischemic                  | 20 (2.7)       | 2 (4.2)     |         |
| Rheumatic                 | 25 (3.3)       | 0 (0.0)     |         |
| Endocarditic              | 75 (10.0)      | 5 (10.4)    |         |
| Other                     | 120 (16.0)     | 9 (18.8)    |         |

Note: In respect to etiology of mitral valve disease the category “other” includes patients with postoperative ring dehiscence, mitral prosthesis degeneration or endocarditis, isolated annular dilatation, etc. The p values that are significant (under .05) are shown in bold.

Abbreviations: COPD, chronic obstructive pulmonary disease; IDDM, insulin-dependent diabetes mellitus; IQR, interquartile range; LVEF, left ventricular ejection fraction; NIDDM, non-insulin-dependent diabetes mellitus; No PPM, patients who did not require pacemaker implantation after surgery; PPM, patients who required pacemaker implantation after surgery.
While pacemaker implantation rates have been investigated previously, most authors present cohorts either comparing multiple surgical procedures or investigating a narrow patient group. Meimoun et al. investigated the rate of AVB after the mitral valve repair using the Carpentier technique finding that 6% developed third-degree AVB. In a randomized controlled trial investigating mitral valve surgery with concomitant ablation (51.8% receiving ablation, 26.3% receiving a biaatrial maze procedure) DeRose et al. report an 11.9% rate of pacemaker implantation during index hospitalization and a 14.4% rate 1 year after surgery. In our study, we elected to investigate a cohort of all patients requiring mitral valve surgery. This allowed us to include various operative predictors in our analysis. In our cohort 64.7% received procedures addressing only the mitral valve.

FIGURE 2 Association of predictor variables with pacemaker implantation after mitral valve surgery in univariable analysis. Odds ratios associated with statistical significance are formatted in bold on the right of the graph. 95% CI, 95% confidence interval; CABG, coronary artery bypass grafting; GFR, glomerular filtration rate; LAA, left atrial appendage; MV, mitral valve; NYHA, functional classification as described by the New York Heart Association

4 | DISCUSSION

While pacemaker implantation rates have been investigated previously, most authors present cohorts either comparing multiple surgical procedures or investigating a narrow patient group. Meimoun et al. investigated the rate of AVB after the mitral valve repair using the Carpentier technique finding that 6% developed third-degree AVB. In a randomized controlled trial investigating mitral valve surgery with concomitant ablation (51.8% receiving ablation, 26.3% receiving a biaatrial maze procedure) DeRose et al. report an 11.9% rate of pacemaker implantation during index hospitalization and a 14.4% rate 1 year after surgery. In our study, we elected to investigate a cohort of all patients requiring mitral valve surgery. This allowed us to include various operative predictors in our analysis. In our cohort 64.7% received procedures addressing only the mitral valve.
30.5% received double valve procedures with 19.2% receiving procedures addressing the mitral and tricuspid valves. In our cohort, 23.8% underwent surgical ablation. We determined a 6.1% pacemaker implantation rate at 30 days, 6.4% rate at 50 days, and a 12.1% rate at 8 years. While it is clear that most pacemakers are implanted within the first weeks after surgery, the risk of bradyarrhythmia does not end at discharge—the "late-presenters" are a group which require further investigation in the future.

### AVB is the most frequent rhythm disorder after mitral valve surgery

In our analysis, we investigated the incidence and risk factors for pacemaker requirement after mitral valve surgery. In our study, this included all forms of bradyarrhythmia leading to pacemaker requirement. The most frequent rhythm disorder was as expected AVB. Sinus node dysfunction and atrial fibrillation with a slow ventricular rate made up the smaller groups. Each of the disorders has its own anatomic and pathophysiological relationship to mitral valve surgery. Sinus node dysfunction may be related to the cannulation technique applied during surgery, to the atriotomy and suture path for atriotomy closure. AVB may be related to the anatomy of the valves and conduction pathways past the valvular structures. Atrial fibrillation on the other hand has a very intimate relationship with mitral valve pathologies and is frequently seen in these patients. We note that a more pathophysiological analysis of the relationships would of course isolate the respective bradyarrhythmias and investigate them individually. It is because of our group size that this was not possible herein. We suggest that this be performed with data aggregated from many centers in the future.

### TABLE 2  Multivariable analysis of predictors of pacemaker requirement after mitral valve surgery

| Variable                        | Odds ratio | 95% confidence interval | p Value |
|---------------------------------|------------|-------------------------|---------|
| Mitral valve replacement        | 1.905      | 1.026–3.536             | .041    |
| Tricuspid valve ring annuloplasty | 2.348      | 1.165–4.730             | .017    |
| Insulin-dependent diabetes mellitus | 4.665      | 1.975–11.017           | .001    |
survival. Most likely the data from the CTSN lead to the conclusion that leads can be considered. Not only is the placement of leads through a pacemaker technically challenging, there is evidence that placement of epicardial leads always weighs the risk and benefit of adding this procedure. Furthermore, especially in such patients the placement of epicardial leads will be complicated.

11.4% required pacemaker implantation. In a time when concomitant tricuspid ring annuloplasty was excluded and only pacemakers implanted before 50 days were allocated to the pacemaker group. No PPM, patients who did not require pacemaker implantation after surgery; PPM, patients who required pacemaker implantation after surgery.

4.2 | Tricuspid ring annuloplasty begets postoperative bradyarrhythmia

It is precisely because we investigated all patients requiring mitral valve surgery and not just those receiving single valve—mitral valve surgery that we were able to investigate various operative predictors. Multivalve surgery has been linked to higher pacemaker implantation rates previously. We also detected a higher rate of multivalve surgery in patients later requiring pacemakers. In multivariable testing, we found a stronger association between pacemaker requirement after surgery and tricuspid ring annuloplasty. It is known that tricuspid valve surgery is associated with pacemaker requirement and high rates have been reported recently. Pathophysiologically the anatomic proximity of the atrioventricular node and Hisian tissue to the tricuspid valve ring is most likely responsible. In a small retrospective study comparing isolated mitral repair with mitral repair combined with tricuspid ring annuloplasty, the latter was found to be associated with a higher rate of conduction disorders. In our cohort, the implantation of a tricuspid annuloplasty ring was associated with an odds ratio of 2.348 (95% CI: 1.65–4.730) for the development of a bradyarrhythmia requiring pacemaker implantation. Without tricuspid ring annuloplasty 5.2% of patients required pacemaker implantation while with annuloplasty 11.4% required pacemaker implantation. In a time when concomitant tricuspid annuloplasty has become more common the surgeon should always weigh the risk and benefit of adding this procedure. Furthermore, especially in such patients the placement of epicardial leads can be considered. Not only is the placement of leads through a reconstructed valve technically challenging, there is evidence that lead-induced regurgitation may be associated with reduced survival. Most likely the data from the CTSN Evaluating the Benefit of Concurrent Tricuspid Valve Repair During Mitral Surgery Trial will enlighten us as to when concomitant tricuspid valve repair is most beneficial for patients requiring mitral surgery.

4.3 | Pacemaker dependent bradyarrhythmia is less likely after mitral valve repair

In our analysis, the type of mitral valve procedure (i.e. repair vs. replacement) was also found to be associated with pacemaker implantation. While not clearly comparing only mitral valve repair with replacement the data presented by Moskowitz et al. provides evidence of higher rates of PPM requirement after replacement (10.5% vs. 4.5% at 1 year). In the randomized trial investigating mitral valve surgery with ablation DeRose et al. report a (nonsignificant) higher ratio of mitral replacement in the PPM group compared with the No PPM group (60% vs. 42%, p = .05). To this point, most studies have shown higher rates of pacemaker implantation after replacement but no study has found statistical significance or even mentioned this association as a relevant result. This is thus a unique finding which we are able to provide. Most likely due to the higher rate of mitral valve repair in patients with mitral valve prolapse we also found a lower rate of mitral valve prolapse in the PPM group. The mitral valve borders the right fibrous trigone at the posteroomedial commissure, an area where the atrioventricular conduction axis traverses. Furthermore, possible proximity of the atrioventricular node artery to the posterior leaflet of the mitral valve and the posteroomedial commissure may also expose it to risk during surgery. Differences in pressure distribution from the implanted prosthesis (ring vs. valve prosthesis) to the surrounding tissue could possibly explain why repair (which almost always involves ring annuloplasty) may be associated with a lower risk of conduction disorders. Further investigations of pressure distribution of various prostheses are required for a better understanding of this issue. Deep sutures required for prosthesis placement could also lead to the damage of the at risk structures mentioned above, and could subsequently result in bradyarrhythmia. In the last decades there has been mounting evidence that mitral valve repair is associated with improved morbidity and mortality—the increased rates of pacemaker requirement after replacement found in our investigation should provide a further stimulus to increase repair rates.

4.4 | Diabetes is associated with conduction disorders

Besides the two operative predictors discussed above, we also identified insulin-dependent diabetes mellitus as a further predictor of pacemaker requirement in multivariable analysis. In their investigation of patients receiving cardiac valve replacement surgery, Leyva et al. similarly identified diabetes mellitus as an independent risk factor for pacemaker requirement. While not commonly known it has been established that conduction disorders are associated with diabetes mellitus. In a population-based cohort study investigating
6,146 community-dwelling individuals, increased fasting glucose levels were associated with the development of AVB.\textsuperscript{17} In a cross-sectional analysis of 845,747 patients at a US Veterans Health Administration hospitals, Movahed et al. found diabetes to be strongly associated with third-degree heart block.\textsuperscript{18} Autonomic neuropathy but also diabetic microangiopathy in conduction tissue\textsuperscript{19} could explain the increased prevalence of AVB in diabetic patients. In our cohort, we were able to detect a higher rate of coronary artery disease (a manifestation of diabetic macroangiopathy) in patients with diabetes mellitus (OR: 2.24; 95% CI: 1.45-3.48). Macroangiopathy affecting vessels supplying conduction tissue could also explain the higher rate of conduction disturbances. The investigation of angiographic data to support this idea was unfortunately not feasible in this study.

4.5 | Euroscore II aggregates several risk factors of pacemaker requirement

Not only does the Euroscore II include diabetes mellitus in score calculation, the score furthermore includes multivalve surgery (weight of intervention), and kidney function (identified as a risk factor in univariable analysis) in the calculation of the score. As such the Euroscore II aggregates several risk factors identified in univariable analysis as predictors of pacemaker requirement. Subsequently, we found the PPM group to have a higher median Euroscore compared with the No PPM group (5.4 vs. 3.2, \( p = .003 \), see Figure 3). Ideally, an investigation of pacemaker implantation rates in various Euroscore II ranges would be performed as to investigate the feasibility of the score as an estimator of risk of conduction disturbances after mitral valve surgery. While this is not feasible with our data set due to the low patient count in the PPM group we recommend that groups to whom large registry datasets are available perform such an analysis as a response to our study results.

4.6 | In our cohort survival is not influenced by pacemaker requirement

In our analysis of survival, comparing patients requiring pacemaker implantation after mitral valve surgery with patients not requiring pacemaker implantation we found no significant difference between the two groups. Numerically a difference could be identified however this difference did not hold in statistical analysis. Raza et al. investigated all patients requiring cardiac surgery at their institution in Minneapolis and found reduced survival among patients who required pacemakers after surgery.\textsuperscript{20} After adjusting for several confounders this difference was however no longer evident. Pacemaker implantation can be associated with several adverse effects, such as venous thrombosis, infection, and tricuspid regurgitation. While implantation must subsequently always be indicated carefully it is reassuring, for both the patient and physician that survival does not suffer significantly when this complication does arise after mitral valve surgery.

4.7 | Limitations

The presented study is retrospective in nature and thus associated with several limitations. The nature of the study especially prohibited an in-depth investigation of electrocardiographic data which was not as abundant as would have been desired by the investigators. No long-term echocardiographic data were available—an area of interest especially in patients requiring trans-tricuspid lead placement. Due to the cohort size only a small group of variables could be tested regarding their relationship to pacemaker requirement in multivariable testing. A topic also not explored due to the insufficiency of data available was post-implant pacemaker dependency. An understanding of the actual pacemaker stimulation rates would greatly add to our understanding of postoperative bradyarrhythmias after mitral valve surgery.

5 | CONCLUSION

Our investigation has demonstrated that in patients requiring any form of mitral valve surgery there are two key operative risk factors: mitral valve replacement and concomitant tricuspid ring annuloplasty. If the patient suffers from diabetes preoperatively an increased risk is also evident. There is sufficient evidence that mitral repair is superior to replacement regarding postoperative morbidity and mortality—herein we provided evidence that shows that repair also has the added benefit of a lower risk of bradyarrhythmia. Repair should be attempted whenever feasible. In an era where concomitant tricuspid annuloplasty is becoming more commonplace, we should still always take time to weigh the benefits and risks of this procedure. The choice to perform concomitant annuloplasty when only little regurgitation is present should always be thought over carefully in light of the significantly increased risk of bradyarrhythmia after annuloplasty. A more concrete idea of how to deal with the tricuspid valve during mitral valve surgery will be available when the data from the CTSN study on concomitant tricuspid repair is published.

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