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Mitral valve replacement with or without a concomitant Maze procedure in patients with atrial fibrillation

Joon Bum Kim,1 Min Ho Ju,1 Sung Cheol Yun,2 Sung Ho Jung,1 Cheol Hyun Chung,1 Suk Jung Choo,1 Taek Yoon Lee,1 Hyun Song,3 Jae Won Lee1

ABSTRACT

Background Although the Maze procedure is regarded as the most effective way to restore sinus rhythm in patients with chronic atrial fibrillation (AF), it remains unclear whether this procedure offers long-term clinical benefits in patients undergoing mechanical valve replacement.

Methods and results Between 1999 and 2007, 402 patients with AF-associated mitral valve (MV) disease underwent MV replacement with a mechanical prosthesis. Of these patients, 159 underwent valve replacement plus the Maze procedure, whereas 243 received valve replacement alone. The composite end-points of cardiac death and cardiac-related morbidities were compared in these two groups using the inverse-probability-of-treatment-weighted method. At a median follow-up time of 63.1 months (range 0.2–123.9 months), patients who had undergone the Maze procedure were at significantly lower risk of thromboembolic events (hazard ratio (HR) = 0.26, 95% confidence interval (CI) 0.07 to 0.95; p = 0.041) and were at comparable risk of cardiac death (HR = 0.96, 95% CI 0.44 to 2.07; p = 0.907) and cardiac death (HR = 1.26, 95% CI 0.53 to 3.01; p = 0.598) compared with patients who underwent MV replacement alone. The composite risk of death or major events was lower in the Maze procedure group (HR = 0.64, 95% CI 0.38 to 1.08; p = 0.093).

Conclusions Compared with MV replacement alone, the addition of the Maze procedure was associated with a reduction in thromboembolic complications and better long-term event-free survival in patients with AF undergoing mechanical MV replacement. Prospective randomised data are necessary to confirm the findings of this study.

INTRODUCTION

In the interval since the Maze operation was introduced for ablation of atrial fibrillation (AF),1 the effectiveness of the operation for sinus rhythm conversion has been well demonstrated, and it has been widely performed in combination with various cardiac operations.2–6 A number of studies have suggested that the incorporation of atrial contractility into cardiac output by use of a successful Maze procedure may improve haemodynamic performance and patient functional status.2 6–8

The long-term clinical benefits of the Maze procedure are, however, uncertain, because it is not known whether the maintenance of sinus rhythm after valve surgery leads to improved survival or helps to prevent embolic complications.3 9–11 Furthermore, the efficacy of the Maze procedure in patients who undergo mechanical valve replacement is still unclear, as the addition of the procedure has not been shown to further reduce thromboembolic risks in patients who require lifelong anticoagulation treatment.10 To the best of our knowledge, the overall long-term clinical benefits of the Maze procedure have not been well evaluated in this patient population. We therefore compared the long-term clinical outcomes of patients with AF receiving mechanical valve replacement alone and those undergoing valve replacement combined with the Maze procedure.

METHODS

Study population

From January 1999 to July 2007, 582 patients with AF-associated mitral valve (MV) disease underwent mechanical MV replacement with or without a concomitant Maze procedure. Patients diagnosed with ischaemic mitral regurgitation or infective endocarditis, and those who underwent concomitant cardiac surgery for congenital heart defects or aortic diseases, were excluded, as were patients who underwent multi-vessel coronary artery bypassing. However, patients with incidental coronary lesions, including a requirement for single-vessel coronary artery bypassing, were not excluded. Of the total of 402 included patients, 159 underwent MV replacement combined with the Maze procedure whereas 243 received MV replacement alone. During the study period, most of the patients with rheumatic MV disease underwent MV replacement rather than repair owing to concerns about disease recurrence and consequent reoperation following the repair procedure.12 For degenerative mitral regurgitation, repair has been the primary surgical option. However, patients with degenerative mitral disease who were included in this study (n = 50) underwent MV replacement for the following reasons: (a) disease which was difficult to correct in 17 and (b) an initial repair had failed in 13. The decision to perform the Maze procedure was at the attending surgeon’s discretion; some authors in this study were prudent in performing the Maze procedure in conjunction with MV replacement using a mechanical prosthesis.

This study was approved by our institutional ethics committee/review board, and the requirement for informed patient consent was waived by the board owing to the retrospective nature of this study.
Echocardiographic evaluation
Two-dimensional echocardiography and Doppler colour flow imaging were performed using Hewlett-Packard Sonos 2500 or 5500 imaging systems equipped with 2.5 MHz transducers (Hewlett-Packard, Andover, Massachusetts, USA). Preoperative echocardiography was performed in all patients within 3 months before surgery. The end-systolic and end-diastolic dimensions of the left ventricle (LV) were measured from parasternal M-mode acquisitions, and end-systolic volume, end-diastolic volume and ejection fraction of the LV were calculated using the biplane Simpson method. Employing the simplified proximal isovelocity surface area (PISA) approach, the degree of mitral regurgitation was classified as grade 1 (PISA radius <4 mm), grade 2 (PISA radius 4–8 mm), or grade 3 (PISA radius >8 mm). MV area was estimated using the pressure halftime method. Left atrium (LA) size was calculated from the anteroposterior diameter on the parasternal long-axis view at end systole. Tricuspid regurgitation was evaluated using the apical four-chamber view, and graded as trace, mild, moderate or severe when the jet area occupied <10%, 10–20%, 20–33% or >33% of the right atrial area, respectively.

Surgical procedures
A median sternotomy approach and conventional ascending aorta and bicaval cannulation were used for all patients. The Maze procedure was performed using a modified Cox–Maze III technique, the details of which have been described previously.5 LA tissue incorporation during pulmonary vein isolation was minimised by tightly encircling the pulmonary vein orifices. The ‘cut and suture’ technique was replaced with ablation using either cryoablation (n=147) or microwave ablation (n=12). Cryoablation was performed at −60°C by applying a 15° angled, 30 mm or 70 mm long freeze tip with a diameter of 9 mm (Frigitronics, Cardiac Cryosurgical System 200; Frigitronics, Cooper Surgical, Shelton, Connecticut, USA), usually for 2 min. Microwave ablation was performed by applying 65 W of microwave energy endocardially for 2 min using FLEX 4 microwave ablation probes (Afx, Fremont, California, USA). Ablation of the right atrial cavo-tricuspid isthmus was performed to postoperative atrial flutter. The surgeons attempted to retain the subvalvular tissue as far as possible in a chordae-sparing manner.

Follow-up
Data were obtained until June 2009 during annual visits to the outpatient clinic. Operative mortality was defined as death within 30 days of surgery, or in hospital. Deaths were classified as cardiac or non-cardiac based on medical records. Data on vital status, dates of death and causes of death were obtained from the Korean national registry of vital statistics. All deaths were considered of cardiac origin unless a non-cardiac origin was established clinically or was determined at autopsy.

Postoperatively, rhythms in patients were monitored daily using standard 12-channel surface electrocardiography (ECG). Follow-up ECGs were performed at 3–6-month intervals during the first 2 years and every year thereafter.

Recurrences or AF events during the initial postablation blanking period of 3 months are defined as ‘early events’.10 Postoperative AF defines any recurrent or persistent AF, atrial tachycardia or atrial flutter beyond the initial blanking period. The results were shown in ‘Freedom from AF’, in which time to first AF events were presented.8

The end point of the study was defined as the composite of cardiac death and cardiac-related morbidities. Cardiac-related morbidities (major morbidities) included ventricular arrhythmia; hospitalisation because of congestive heart failure (CHF); and valve-related complications including thromboembolic events, infective endocarditis, bleeding complications secondary to anticoagulation or a requirement for reoperation during follow-up. A CHF hospitalisation was defined as an unplanned, urgent admission for management of CHF. Any patient admitted for CHF had to show resting dyspnoea and radiological signs of pulmonary oedema, and had to require intravenous diuretics. Bleeding secondary to anticoagulation was defined as any requirement for transfusion, unplanned hospital admission or a haemostatic intervention. Anticoagulation treatment was adjusted during outpatient visits at 3-month intervals to achieve a target international normalised ratio (INR) of 2.0–3.0, regardless of cardiac rhythm status. Patients with inadequate INR values attended weekly or monthly until the target INR value was achieved.

Statistical analysis
Categorical variables are presented as frequencies and percentages, and continuous variables are expressed as mean±SD or medians with ranges. Differences in baseline clinical and echocardiographic characteristics between patients who did or did not undergo the Maze procedure were compared using the t test or the Mann–Whitney U test for continuous variables and the χ² test or Fisher’s exact test for categorical variables, as appropriate. Cumulative incidence rates of individual and composite outcomes were estimated by the Kaplan–Meier method and compared by the log-rank test.

To reduce the impact of treatment selection bias and potential confounding in an observational study, we performed rigorous adjustment for significant differences in patient characteristics by using weighted Cox proportional-hazards regression models and inverse-probability-of-treatment weighting (IPTW).13 14 With that technique, weights for patients receiving MV replacement alone were the inverse of 1 − propensity score, and weights for patients receiving both the Maze procedure and MV replacement were the inverse of the propensity score. The propensity scores were estimated by multiple logistic-regression analysis.15 All prespecified covariates were included in full non-parsimonious models for MV replacement plus the Maze procedure, versus MV replacement alone (table 1). The discrimination and calibration abilities of each propensity score model were assessed by C statistics and the Hosmer–Lemeshow test. The model was well calibrated (Hosmer–Lemeshow test; p=0.868) with reasonable discrimination (C statistic=0.745).

In addition, for more rigorous adjustment to avoid selection bias and profiles effects, a second Cox model was created with IPTW as the weights, treatment effect (MV replacement plus the Maze procedure or MV replacement alone) and some important risk covariates, which had significant effects (p<0.1) on the clinical outcomes. All reported p values are two sided, and values of p<0.05 were considered to indicate statistical significance. SAS software version 9.1 (SAS Inc) was used for statistical analysis.

RESULTS
Baseline profiles
Baseline characteristics of patients are shown in table 1. Patients who underwent a concomitant Maze procedure were younger, more likely to have simultaneous coronary disease, more likely to undergo concomitant tricuspid annuloplasty and less likely to have degenerative MV pathology than those who underwent MV replacement alone. Follow-up was complete in 372 patients (92.5%) with a median follow-up duration of 65.1 months (range 0.2–125.9 months).
Heart rhythm disorders

Table 1  Baseline characteristics of all patients.

<table>
<thead>
<tr>
<th></th>
<th>Maze group</th>
<th>Non-Maze group</th>
<th>p</th>
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<tbody>
<tr>
<td>Number of patients, n</td>
<td>159</td>
<td>243</td>
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<tr>
<td>Age, years</td>
<td>49.6±9.7</td>
<td>52.6±10.0</td>
<td>0.003*</td>
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<tr>
<td>Male gender, n (%)</td>
<td>57 (35.8)</td>
<td>90 (37.0)</td>
<td>0.809</td>
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<tr>
<td>Diabetes mellitus, n (%)</td>
<td>7 (4.4)</td>
<td>9 (3.7)</td>
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<td>Hypertension, n (%)</td>
<td>9 (5.7)</td>
<td>19 (7.8)</td>
<td>0.432</td>
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<td>Single-vessel coronary disease, n (%)</td>
<td>9 (5.7)</td>
<td>4 (1.6)</td>
<td>0.040*</td>
</tr>
<tr>
<td>Previous PMV, n (%)</td>
<td>17 (10.7)</td>
<td>31 (12.8)</td>
<td>0.533</td>
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<tr>
<td>History of thromboembolism, n (%)</td>
<td>19 (11.9)</td>
<td>29 (11.9)</td>
<td>0.996</td>
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<tr>
<td>Cerebrovascular accident</td>
<td>16</td>
<td>20</td>
<td></td>
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<tr>
<td>Peripheral thromboembolism</td>
<td>3</td>
<td>9</td>
<td>0.261</td>
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<td>Mitral valve stenosis, n (%)</td>
<td>1</td>
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Echocardiographic data

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<tr>
<td>Mitral diagnosis, n (%)</td>
<td>43 (27.0)</td>
<td>75 (30.9)</td>
<td>0.817</td>
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<tr>
<td>2</td>
<td>27 (17.0)</td>
<td>33 (13.6)</td>
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<tr>
<td>3</td>
<td>22 (13.8)</td>
<td>29 (11.9)</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>39 (24.5)</td>
<td>61 (23.1)</td>
<td></td>
</tr>
<tr>
<td>Trans-mitral peak PG, mm Hg</td>
<td>20.5±10.4</td>
<td>19.9±9.9</td>
<td>0.595</td>
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<tr>
<td>Mitral valve area, cm²</td>
<td>1.4±0.9</td>
<td>1.4±0.9</td>
<td>0.826</td>
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<tr>
<td>Tricuspid regurgitation grade, n (%)</td>
<td>50 (31.4)</td>
<td>94 (38.7)</td>
<td>0.116</td>
</tr>
<tr>
<td>2</td>
<td>34 (21.4)</td>
<td>55 (22.6)</td>
<td></td>
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<tr>
<td>3</td>
<td>35 (22.0)</td>
<td>40 (16.5)</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>40 (25.2)</td>
<td>49 (20.2)</td>
<td></td>
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<tr>
<td>LV ejection fraction, %</td>
<td>54.0±6.5</td>
<td>54.5±9.4</td>
<td>0.583</td>
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<tr>
<td>LV end-systolic dimension, mm</td>
<td>38.3±7.2</td>
<td>37.0±7.5</td>
<td>0.083</td>
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<tr>
<td>LV end-diastolic dimension, mm</td>
<td>54.3±8.0</td>
<td>53.2±9.0</td>
<td>0.222</td>
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<tr>
<td>Left atrial dimension, mm</td>
<td>59.6±9.1</td>
<td>60.2±8.8</td>
<td>0.779</td>
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<tr>
<td>Trans-tricuspid peak PG, mm Hg</td>
<td>36.4±12.5</td>
<td>37.6±15.9</td>
<td>0.416</td>
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AF profiles

<table>
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<th></th>
<th>Maze group</th>
<th>Non-Maze group</th>
<th>p</th>
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<tr>
<td>AF duration, years, median (range)</td>
<td>4 (0–40)</td>
<td>4 (0–28)</td>
<td>0.879</td>
</tr>
<tr>
<td>Fine (&lt;1 mm) AF wave, n (%)</td>
<td>60 (37.7)</td>
<td>95 (38.1)</td>
<td>0.784</td>
</tr>
<tr>
<td>AF type, n (%)</td>
<td>33 (20.0)</td>
<td>40 (16.5)</td>
<td>0.653</td>
</tr>
<tr>
<td>Paroxysmal</td>
<td>15 (9.8)</td>
<td>11 (4.5)</td>
<td></td>
</tr>
<tr>
<td>Persistent (&lt;1year)</td>
<td>46 (28.9)</td>
<td>46 (28.3)</td>
<td></td>
</tr>
<tr>
<td>Longstanding (&gt;1year) persistent</td>
<td>105 (66.0)</td>
<td>170 (70.0)</td>
<td></td>
</tr>
<tr>
<td>Concomitant aortic valve replacement, n (%)</td>
<td>46 (28.9)</td>
<td>71 (28.2)</td>
<td>0.517</td>
</tr>
<tr>
<td>Concomitant tricuspid valve repair, n (%)</td>
<td>100 (62.9)</td>
<td>86 (35.4)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>EuroSCORE</td>
<td>2.80±1.53</td>
<td>2.77±1.45</td>
<td>0.834</td>
</tr>
</tbody>
</table>

*p < 0.05.
AF, atrial fibrillation; LV, left ventricular; PG, pressure gradient; PMV, percutaneous mitral valvotomy.

Outcomes

Perioperative results

Aortic clamping and cardiopulmonary bypass times were significantly longer in the Maze than in the non-Maze group (aortic clamping time: 113.9±28.1 min vs 73.5±48.2 min, p <0.001; cardiopulmonary bypass time: 161.9±41.0 min versus 117.0±69.9 min, p <0.001). There were five early deaths (1.24%), but no significant difference in operative mortality or morbidity between the two groups (table 2).

Rhythm outcomes

Of the 397 early survivors, cardiac rhythm follow-up over 3 months was possible in 376 patients (95.5%; 152 in Maze group and 224 in non-Maze group) with a mean rhythm follow-up duration of 50.1±32.7 months. Overall, 3520 12-lead-ECGs (1526 (9.6/patient) in the Maze group and 1794 (7.4/patient) in the non-Maze group) and 211 sets of 24 h Holter monitoring data (199 in the Maze group, and 12 in the non-Maze group) were obtained for rhythm analyses.

In the Maze group, 55 patients (23.5%) experienced early AF events. All of the late-follow-up patients in the Maze group eventually showed normal sinus rhythm at least once postoperatively, except for five who underwent permanent pacemaker implantation. Of the patients for whom sinus rhythm was restored (n=144), 21 showed late AF recurrence (14.6%).

In the non-Maze group, 53 patients (15.1%) restored normal sinus rhythm without any recurrence of AF, and 146 patients (67.0%) showed paroxysmal AF following surgery. Thirty-seven (17.0%) patients in the non-Maze group showed persistent AF postoperatively.

The 3- and 5-year rates of freedom from AF were 86.0±3.2% and 82.1±4.1% in the Maze group, and 23.2±2.9% and 17.3±2.8% in the MVR group, respectively (p <0.001; figure 1). Table 3 describes the last follow-up cardiac rhythm status.

Unadjusted clinical outcomes

There were 26 late deaths including 16 cardiac deaths. Non-cardiac causes of death were malignancy in seven, underlying end-stage renal disease in one, underlying polymyositis in one and traffic accident in one patient.

Incidence of late events are shown in table 4. Of the patients who had thromboembolic complications (n=15), anti-coagulation status at the time of the events could be obtained in 14 (three in the Maze group and 11 in the non-Maze group). Of these, only four (all in the non-Maze group) were within an acceptable INR level (2.05–3.10), whereas the other 10 had an INR level of 0.96–1.53 (median 1.22, three in the Maze group and seven in the non-Maze group). Ten patients in the group undergoing an MV replacement alone required cardiac

Figure 1 Freedom from postoperative atrial fibrillation (AF).
reoperation—five for progression of tricuspid regurgitation, three for paravalvular leakage, one for prosthetic valve thrombosis and one for LV rupture. Figure 2 depicts the unadjusted freedom from all-cause death, cardiac death, and major valve-related complications. The Maze and non-Maze groups showed comparable freedom from all-cause death (HR = 0.97, 95% CI 0.46 to 2.03; p = 0.715), cardiac death (HR = 1.30, 95% CI 0.55 to 3.09; p = 0.932), thromboembolic events (HR = 0.42, 95% CI 0.12 to 2.49; p = 0.069), reoperation (HR = 0.02, 95% CI 0.01 to 3.65; p = 0.15), and the composite of cardiac death and major complications (HR = 0.80, 95% CI 0.50 to 1.27, p = 0.140).

Adjusted hazards
Table 5 summarises the cumulative hazard of adverse outcomes in patients undergoing MV replacement plus the Maze procedure, versus MV replacement alone, using adjusted multivariable analyses. When patient outcomes were adjusted using IPTW, patients undergoing the concomitant Maze procedure were at a significantly lower risk of thromboembolic events, and a comparable risk of death or cardiac death, in the first and second multivariable Cox model, compared with the non-Maze group. The risk of the composite of cardiac death and major events was somewhat lower for the Maze group, with marginal significance (p = 0.092 and 0.093 in the first and second multivariable Cox models, respectively).

Comparison of end points according to postoperative rhythm status
Of the 367 late rhythm follow-up patients, patients who had persistent or late recurrent AF (n = 204; 21 in the Maze group and 183 in the non-Maze group) were compared with those without AF recurrence (n = 163; 128 in the Maze group and 55 in non-Maze group) for clinical end points. It was found that patients without postoperative AF were at a significantly lower risk of thromboembolic events (HR = 0.24, 95% CI 0.05 to 0.99; p = 0.044). The risk of death (HR = 0.36, 95% CI 0.12 to 1.08; p = 0.058), cardiac death (HR = 0.35, 95% CI 0.08 to 1.63; p = 0.161) and the composite of cardiac death and major events (HR = 0.65, 95% CI 0.38 to 1.10; p = 0.108) tended to be lower for the patients without postoperative AF (figure 3).

DISCUSSION
This study demonstrated that patients with AF who underwent MV replacement combined with the Maze procedure had greater freedom from thromboembolic complications than those who underwent MV replacement alone. The addition of the Maze procedure was not associated with increased operative morbidity or mortality despite the longer cardiac ischaemic time required.
Long-term survival was comparable in both patient groups. Better clinical outcomes were evident in patients who remained in normal sinus rhythm than in those with persistent or recurrent AF postoperatively.

The Cox–Maze procedure is the most effective surgical procedure for terminating AF. This procedure is reported to have several clinical benefits, including eliminating the symptoms of irregular rhythms, and incorporating atrial contractility into cardiac output, thus improving overall haemodynamics. Restoration of atrial contraction may further eliminate the source of mural thrombus formation.

Concerns have arisen, however, that a combination of MV replacement and the Maze procedure will increase early morbidity and mortality because addition of the Maze procedure to MV surgery complicates the operation, inevitably resulting in prolonged cardiac ischaemic and cardiopulmonary bypass times. Furthermore, it is not clear whether maintaining sinus rhythm after valve surgery leads to improved survival or helps to prevent embolic complications.

To assess the risks and benefits of adding the Maze procedure, several retrospective studies have compared the outcomes of patients receiving a combined Maze procedure with those undergoing isolated MV surgery. The cited studies, however, had small numbers of patients, heterogeneous study populations (mixed mitral repair and replacement), short follow-up duration and/or insufficient adjustment for baseline risk profiles.

Evaluations of clinical outcomes after the combined Maze procedure in patients undergoing mechanical valve replacement differs from assessment after valve repair or bioprosthetic valve replacement because patients who undergo mechanical valve replacement require lifelong anticoagulation treatment. Anticoagulation treatment after valve replacement may be sufficient to prevent thromboembolic events, even without restoration of normal sinus rhythm. Furthermore, the outcome of the Maze operation may be less than optimal in patients with advanced MV pathology that is not reparable. Because MV replacement is indicated only in patients with advanced MV pathology that is difficult to correct, such patients probably have more advanced atrial pathology that is arrhythmogenic, suggesting that such patients may respond poorly to AF ablation surgery.

A study comparing the outcomes of patients with AF who underwent either MV replacement alone, MV repair plus the Maze operation, or MV replacement plus the Maze operation, found that omission of the Maze procedure was the only significant risk factor for late stroke. Similar findings have been observed in another report, which found that stroke risk remained high in patients with an MV replacement receiving anticoagulation treatment, and that this risk was reduced when sinus rhythm was restored.

We made efforts to overcome the limitations of previous studies evaluating the clinical efficacy of the Maze procedure in MV surgery. To minimise the confounding effects of baseline variables, we used homogeneous patient populations, requiring only mechanical valve replacement. Patients who underwent concomitant cardiac procedures for aortic, coronary diseases or congenital heart diseases were excluded. Further, to reduce the impact of treatment selection bias, we performed a two-stage

| Table 5 Hazard ratios (HRs) for clinical outcomes with the combined Maze procedure versus mitral replacement alone |
|-----------------------------------------------|-----------------------------------------------|
| Table 5 Hazard ratios (HRs) for clinical outcomes with the combined Maze procedure versus mitral replacement alone |
| Outcomes | Adjusted by IPTW | HR 95% CI p | Adjusted by IPTW and covariates* | HR 95% CI p |
| All-cause death† | 0.79 | 0.37 to 1.69 | 0.365 | 0.96 | 0.44 to 2.07 | 0.907 |
| Cardiac death‡ | 1.05 | 0.44 to 2.53 | 0.912 | 1.26 | 0.53 to 3.01 | 0.598 |
| Thromboembolism§ | 0.28 | 0.07 to 0.95 | 0.041 | 0.26 | 0.07 to 0.95 | 0.041 |
| Cardiac death/major events¶ | 0.64 | 0.38 to 1.08 | 0.093 | 0.64 | 0.38 to 1.08 | 0.093 |

*Findings were adjusted by IPTW and incorporate significant covariates influencing outcomes, including.
†age, diabetes mellitus.
‡age, tricuspid valve repair.
§none.
¶diabetes mellitus, redo surgery, tricuspid valve repair.

Figure 3 Clinical outcomes according to postoperative cardiac rhythm status (non-AF recurrence group vs postoperative AF group). (A) Overall survival. (B) Freedom from cardiac mortality. (C) Freedom from thromboembolic complications. (D) Freedom from cardiac deaths and major morbidities. AF, atrial fibrillation.
adjustment for significant differences in baseline patient characteristics by use of the weighted Cox proportional-hazards regression models using IPTW. 13,14

Our finding that the Maze procedure reduced long-term thromboembolic complications differed from the results of a prospective randomised trial involving patients with isolated AF, which reported that rate management yielded outcomes comparable to those seen with rhythm management. 23 This difference may be attributable to differences in study populations, and variation in the ability of treatments to restore sinus rhythm. In the cited study, the prevalence of sinus rhythm in the rhythm-control group was only 62.6% at 5 years, whereas freedom from any AF during 5-year follow-up was 82.1% in our patient population. This difference reflects the better efficacy of the Maze procedure compared with medical treatment in eliminating AF, resulting in improved prevention of thromboembolic events.

Study limitations

This study is subject to the limitations inherent in retrospective work with observational data. The non-randomised design may have affected the results because of unmeasured confounders, procedure bias or detection bias, even with the use of rigorous statistical adjustment.

CONCLUSIONS

Compared with MV replacement alone, addition of the Maze procedure was associated with a reduction in thromboembolic complications and offered a modest benefit for event-free survival in patients with AF undergoing mechanical MV replacement. The better clinical results with the Maze procedure were attributed to the maintenance of sinus rhythm, evidenced by a lower rate of thromboembolic complications found in patients who were kept in normal sinus rhythm. Prospective randomised data are necessary to confirm the findings of this study.

Competing interests

None.

Ethics approval

This study was conducted with the approval of the ethics committee/review board of Asan Medical Center, Seoul, Korea.

Provenance and peer review

Not commissioned; externally peer reviewed.

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