Surgery for Valvular Heart Disease

Reoperation of Left Heart Valve Bioprostheses According to Age at Implantation

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Background—Evidence supporting the use of bioprostheses for heart valve replacement in young adults is accumulating. However, reoperation data, which may help guide clinical decision making in young patients, remains poorly defined in the literature.

Methods and Results—We examined the need for reoperation in 3975 patients who underwent first-time bioprosthetic aortic valve replacement (AVR) (n = 3152) or mitral valve replacement (MVR) (n = 823). There were 895 patients below the age of 60 years at bioprosthesis implant (AVR, n = 636; MVR, n = 259). The median interval to reoperation of contemporary, stented aortic bioprostheses was 7.74 years (95% CI 7.28 to 9.97 years) in patients less than 40 years, and 12.93 years (95% CI 11.10 to 15.76 years) in patients between 40 and 60 years of age. Multivariable risk factors associated with reoperation following bioprosthetic AVR include age (hazard ratio [HR] 0.94 per year, 95% CI 0.91 to 0.96, P < 0.001) and concomitant coronary artery bypass grafting (HR 0.34, 95% CI 0.11 to 0.99, P = 0.04). The median interval to reoperation of contemporary mitral bioprostheses was 8.11 years (95% CI 5.79 to 16.50 years) in patients less than 40 years, and 10.14 years (95% CI 8.64 to 11.14 years) in patients between 40 and 60 years of age. As for AVR, age (HR 0.96 per year, 95% CI 0.95 to 0.98, P < 0.001) and concomitant coronary artery bypass grafting (HR 0.55, 95% CI 0.32 to 0.93, P = 0.03) were associated with decreased reoperation risk following bioprosthetic MVR.

Conclusions—These data constitute clinically relevant age-specific prognostic information regarding reoperation in young patients, who may wish to select a bioprosthesis at initial left heart valve replacement. (Circulation. 2011; 124[suppl 1]:S75–S80.)

Key Words: aortic valve ■ bioprosthesis ■ mitral valve ■ reoperation ■ surgery, general

Bioprostheses are the device of choice for older patients who require heart valve replacement.1 Large cohort studies have indicated that excellent survival and freedom from valve-related complications, including reoperation, are associated with the use of a bioprosthesis for left heart valve replacement in patients older than 65 years.2–8 Younger patients also may opt for a bioprosthesis at the time of valve surgery to avoid long-term oral anticoagulation, which is associated with hemorrhage and worse disease perception.9 Recent North American data indicate that bioprostheses are increasingly used in patients less than 65 years of age who undergo aortic valve replacement (AVR) or mitral valve replacement (MVR).10–12

We and others have shown that patients between 18 and 60 years of age who select a bioprosthesis at the time of initial heart valve surgery have an increased reoperation risk but experience no long-term survival detriment compared with patients who select a mechanical valve.4,13 It has been long known that younger patients generally have lower freedom from structural valve deterioration and valve-related reoperation2,14,15 than older patients, but studies so far have not stratified specific age groups below 65 years. Indeed, it remains unclear as to exactly how long a bioprosthesis may last when it is implanted in a patient in his or her fifth or sixth decade of life.2–8,13–15 Accurate reoperation information would be important for patients who present for valve replacement surgery at a young age, as well as for the physicians who treat them.

We performed an observational study of 3975 patients undergoing bioprosthetic left heart valve replacement to evaluate the freedom from reoperation, according to the age of the patient at initial implantation.

Methods

Ethics Approval and Funding

The University of Ottawa Heart Institute has existing ethics approval from its institutional research ethics board to anonymously publish data that are prospectively collected before and after heart valve replacement.
replacement. As such, individual patient consent was waived. The University of Ottawa Heart Valve Clinic receives unrestricted research funding from Edwards Lifesciences, Medtronic, and On-X Life Technologies.

Patient Population
Between 1976 and 2010, 3975 patients underwent bioprosthetic valve replacement with either an aortic valve (n=3152) or a mitral valve (n=823). Patients who received concomitant AVR and MVR were excluded. The decision to implant a bioprosthesis was according to the patient’s preference or, in rare unexpected or emergency situations, according to the surgeon’s preference. The decision to undergo subsequent reoperation was made considering current practice guidelines, the willingness of the patient and family to undergo reoperation, and patient comorbid and surgical factors that would influence the technical feasibility of reoperation. Baseline patient characteristics are described in Table 1, and the valve prostheses implanted are described in Table 2.

Follow-up
The University of Ottawa Heart Valve Clinic prospectively follows all patients after valve replacement surgery. This includes annual assessments for prostheses-related complications, which are defined according to the “Guidelines for Reporting Mortality and Morbidity after Cardiac Valve Interventions,” as well as telephone interviews. Follow-up information was also obtained through electronic medical records. The mean follow-up duration was for 5.8±4.6 years (median 5.1 years, 25th to 75th percentile 2.1 to 9.2 years, maximum 28.2 years).

Statistical Analysis
Data were imported and analyzed in Stata data analysis and statistical software version 11.1, StataCorp (College Station, TX). The baseline characteristics of patients who underwent AVR or MVR were compared across 3 age strata, defined a priori as less than 40 years of age, between 40 and 60 years of age, and greater than 60 years of age at initial valve implantation. The upper age limit of 60 years was selected based on previously published data describing outcomes in young patients. Separate Wilcoxon rank sum tests were used as a test for trend to compare baseline categorical variables across age categories.

The Kaplan-Meier method was used to assess freedom from reoperation among patients who underwent AVR or MVR. Ten- and 15-year freedom from reoperation following AVR or MVR was then compared across various age cutoffs. Risk factors associated with reoperation following bioprosthetic AVR or MVR were determined by using separate Cox proportional hazards models. The proportional hazards assumption was verified with Schoenfeld residuals. Models were constructed by incorporating (1) variables with P<0.10 on log-rank testing, and (2) previously described risk factors associated with reoperation for patients undergoing AVR or MVR. Analyses were subsequently restricted to include only contemporary prostheses. In this study, contemporary stented aortic bioprostheses included the Carpenter-Edwards Perimount (Baxter Healthcare Corp, Irvine, CA) and the Medtronic Hancock II (Minneapolis, MN). Contemporary mitral bioprostheses included the Edwards Lifesciences Pericardial (Baxter Healthcare Corp), Medtronic Hancock II, and Medtronic Mosaic.

Risk factors associated with reoperation following AVR or MVR were also determined by considering the competing risk of death. This was performed with separate competing risks regression models using Stata data analysis and statistical software version 11.1, StataCorp (College Station, TX) using the formula described by Fine and Gray.

Table 1. Patient and Operative Characteristics

<table>
<thead>
<tr>
<th>Age</th>
<th>Bioprosthetic aortic valve replacement</th>
<th>Atrial fibrillation†</th>
<th>Concomitant CABG</th>
<th>Female gender</th>
<th>Preoperative LVEF =35%</th>
<th>Bioprosthetic mitral valve replacement</th>
<th>Atrial fibrillation†</th>
<th>Concomitant CABG</th>
<th>Female gender</th>
<th>Preoperative LVEF =35%</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n=147</td>
<td>1 (0.7%)</td>
<td>3 (2%)</td>
<td>25 (17%)</td>
<td>18 (12%)</td>
<td>n=46</td>
<td>1 (2%)</td>
<td>2 (4%)</td>
<td>29 (63%)</td>
<td>8 (18%)</td>
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</table>

Table 2. Heart Valve Bioprostheses Implanted

<table>
<thead>
<tr>
<th>Bioprosthetic type</th>
<th>No.</th>
<th>Percentage of Total (%)</th>
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<tbody>
<tr>
<td>Aortic valve replacement</td>
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<td>32</td>
</tr>
<tr>
<td>Edwards Lifesciences Perimount†</td>
<td>1006</td>
<td>9</td>
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<tr>
<td>Edwards Lifesciences Standard Porcine*</td>
<td>9</td>
<td>0.3</td>
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<tr>
<td>Autograft/homograft</td>
<td>176</td>
<td>6</td>
</tr>
<tr>
<td>Ionescu-Shiley‡</td>
<td>491</td>
<td>16</td>
</tr>
<tr>
<td>Medtronic Hancock Modified Orifice§</td>
<td>137</td>
<td>4</td>
</tr>
<tr>
<td>Medtronic Hancock IlI±</td>
<td>1152</td>
<td>37</td>
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<tr>
<td>Medtronic Intact§</td>
<td>103</td>
<td>3</td>
</tr>
<tr>
<td>Stentless prosthesis¶</td>
<td>78</td>
<td>2</td>
</tr>
<tr>
<td>Mitral valve replacement</td>
<td>823</td>
<td>7</td>
</tr>
<tr>
<td>Edwards Lifesciences Pericardial†</td>
<td>61</td>
<td>7</td>
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<tr>
<td>Ionescu-Shiley‡</td>
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<td>Medtronic Hancock Il</td>
<td>3</td>
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<tr>
<td>Medtronic Hancock IlI§</td>
<td>488</td>
<td>59</td>
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<tr>
<td>Medtronic Intact§</td>
<td>30</td>
<td>4</td>
</tr>
<tr>
<td>Medtronic Mosaic†§</td>
<td>2</td>
<td>0.2</td>
</tr>
</tbody>
</table>

*Edwards Lifesciences, Baxter Healthcare Corp, Irvine, CA.
†Contemporary stented bioprostheses.
‡Ionescu-Shiley Laboratories, Irvine, CA.
§Medtronic Inc, Minneapolis, MN.
¶Includes 54 replacements with the Medtronic Freestyle (Medtronic Inc, Minneapolis, MN) and 24 replacements with the Toronto SPV valve (Toronto, ON).
Results

Preoperative and Operative Characteristics
Table 1 outlines the preoperative and operative characteristics of patients following bioprosthetic AVR or MVR. In patients who underwent bioprosthetic AVR, those less than 40 years of age were less likely to be female, to have preoperative atrial fibrillation, and to undergo concomitant coronary artery bypass grafting (CABG) (all P<0.001). There was a trend for better preoperative left ventricle ejection fraction in younger patients; however, this difference was not statistically significant. Among patients who underwent bioprosthetic MVR, those less than 40 years of age were less likely to undergo concomitant CABG compared with older patients (P<0.001).

Outcomes

AVR
Of the 3152 patients who underwent bioprosthetic AVR, 294 subsequently underwent aortic valve reoperation. Of these, 58 were less than 40 years, 148 were between 40 and 60 years, and 88 were more than 60 years of age at initial AVR. Ten- and 15-year freedom from reoperation was 78.96±1.45% and 54.69±2.50% following bioprosthetic AVR. In patients less than 40 years of age, 10-year freedom from reoperation was 50.85±5.79%, whereas 10-year freedom from reoperation in patients between 40 and 60 years of age was 63.21±3.17%. Patients greater than 60 years of age had better freedom from reoperation compared with younger patients (P<0.001), with 10- and 15-year freedom from reoperation of 99.65±1.35% and 78.76±2.86%, respectively (Figure 1A). Patients between 40 and 60 years of age also showed a trend toward better freedom from reoperation compared with patients less than 40 years of age (hazard ratio [HR] 0.67, 95% CI 0.45 to 0.99, P=0.05). For the entire cohort, 10- and 15-year freedom from reoperation following bioprosthetic AVR was >90% in patients greater than 65 years of age (Figure 2A). Qualitatively, the 10-year freedom from reoperation improved linearly with age at bioprosthetic AVR. The 10- and 15-year freedom from reoperation following bioprosthetic AVR was similar in patients greater than 70 years of age (Figure 2A).

The median interval to reoperation following bioprosthetic AVR was 10.27 years (95% CI 8.48 to 12.08 years) in patients less than 40 years of age, and 11.48 years (95% CI 10.47 to 13.07 years) in patients between 40 and 60 years of age. Notably, the median interval to reoperation was not reached in patients more than 60 years of age. When restricting the analyses to patients who had contemporary stented bioprostheses, the median interval to reoperation in patients between 40 and 60 years of age was 12.93 years (95% CI 11.10 to 15.76 years), and it was 7.74 years (95% CI 7.28 to 9.97 years) in patients less than 40 years of age (Figure 1B).

Univariable risk factors associated with reoperation following AVR with a contemporary, stented bioprosthesis included age and concomitant CABG (Table 3). On multivariable analysis, age and concomitant CABG remained the only significant risk factors. For each additional year of age at initial operation, patients were 6% less likely to require subsequent reoperation. Patients who received concomitant CABG were also less likely to undergo subsequent reoperation (Table 3).

Five hundred thirty deaths occurred in patients who did not require aortic valve replacement. In them, the causes of death were accident in 3, cancer in 65, cardiac-related in 105, multiorgan failure in 36, renal failure in 10, respiratory failure in 12, valve-related in 44 (includes cerebrovascular accident in 31, peripheral thromboembolism in 3, prosthetic valve endocarditis in 7, and structural valve deterioration in 3), and unknown/other causes in 254 patients. A multivariable competing risks regression also revealed that age (HR 0.94, 95% CI 0.93 to 0.95, P<0.001) and concomitant CABG (HR 0.52, 95% CI 0.34 to 0.81, P=0.003) were associated with reoperation following bioprosthetic AVR, whereas female gender (HR 0.97, 95% CI 0.70 to 1.34, P=0.9) was not.

Mitral Valve Replacement
Of the 823 patients who underwent bioprosthetic MVR, 144 subsequently underwent mitral valve reoperation. Of these, 23 were less than 40 years, 91 were between 40 and 60 years, and 30 were more than 60 years of age at operation. Qualitatively, the 15-year freedom from reoperation was >80% in patients greater than 65 years of age (Figure 2B). The median interval to reoperation of bioprostheses in the
mitral position in patients less than 40 years of age was 9.49 years (95% CI 7.59 to 15.01 years), and 11.31 years (95% CI 10.25 to 12.51 years) in patients between 40 and 60 years of age (Figure 3A). Patients greater than 60 years of age at the time of bioprosthetic MVR had better freedom from reoperation compared with younger patients \((P < 0.001)\). The freedom from reoperation in patients between 40 and 60 years, however, was not different from that of patients less than 40 years of age \((P = 0.84)\).

The median interval to reoperation of contemporary mitral bioprostheses was 8.11 years (95% CI 5.79 to 16.50 years) in patients less than 40 years of age and 10.14 years (95% CI 8.64 to 11.14 years) in patients between 40 and 60 years of age (Figure 3B). As with bioprosthetic AVR, the median interval to reoperation was not reached for patients greater than 60 years of age. Advanced age and concomitant CABG were also risk factors inversely related to subsequent mitral valve reoperation (Table 4).

Two hundred twelve deaths occurred in patients who did not undergo mitral valve reoperation. The causes of death were accident in 1, cancer in 29, cardiac-related in 41, multiorgan failure in 15, renal failure in 2, respiratory failure in 3, sepsis in 2, valve-related in 22 (includes cerebrovascular accident in 13, peripheral thromboembolism in 2, prosthetic

![Figure 2](image-url)

Figure 2. Freedom from reoperation according to age at operation. Ten- and 15-year freedom (95% CI) from reoperation was determined for patients following bioprosthetic aortic valve replacement (AVR) (A) and mitral valve replacement (MVR) (B). Freedom from reoperation was calculated from the entire cohort of patients, which includes 294 reoperations from the 3152 patients who underwent bioprosthetic AVR and 144 reoperations from 823 patients who underwent bioprosthetic MVR.

![Figure 3](image-url)

Figure 3. Reoperation after bioprosthetic mitral valve replacement (MVR). The freedom from reoperation was determined for patients according to the age at initial MVR. These patients did not receive concomitant aortic valve replacement. A, 144 reoperations for the 823 patients who underwent bioprosthetic MVR. B, 44 reoperations for the 551 patients who underwent bioprosthetic MVR with contemporary bioprostheses.

| Table 3. Risk Factors Associated With Reoperation After Bioprosthetic AVR |
|-----------------------------|-----------------|-----|-----|
| Hazard Ratio                | 95% CI          | P   |
| Univariable*                |                 |     |
| Age (per increasing year)   | 0.92            | 0.90 to 0.95 | <0.001 |
| Concomitant CABG†           | 0.21            | 0.07 to 0.62 | 0.005  |
| Female gender               | 0.42            | 0.16 to 1.13 | 0.09   |
| Preoperative atrial fibrillation‡ | 1.43          | 0.23 to 10.30 | 0.82   |
| Preoperative ejection fraction ≤35% | 0.82          | 0.10 to 6.66 | 0.85   |
| Multivariable*              |                 |     |
| Age (per increasing year)   | 0.94            | 0.91 to 0.96 | <0.001 |
| Concomitant CABG†           | 0.34            | 0.11 to 0.99 | 0.04   |
| Female gender               | 0.57            | 0.20 to 1.60 | 0.29   |

AVR indicates aortic valve replacement; CABG, coronary artery bypass grafting.

*Model developed by incorporating contemporary bioprostheses only.
†Entered into model as a dichotomous variable.
‡Includes preoperative permanent and known paroxysmal atrial fibrillation.
valve endocarditis in 3, and valve thrombosis in 4), and
unknown/other causes in 97 patients. A multivariable com-
peting risks regression revealed that age (HR 0.96, 95% CI
0.95 to 0.98), P<0.001) and concomitant CABG (HR 0.09,
95% CI 0.02 to 0.37, P=0.001) were associated with reop-
eration following bioprosthetic MVR, whereas female gender
(HR 1.71, 95% CI 1.01 to 2.91, P=0.05) was not.

Discussion

We performed an observational study of 3975 patients who
underwent bioprosthetic left heart valve replacement to eval-
uate the need for reoperation according to the age of the
patient at initial implantation.

The preoperative demographics of patients in this study
were similar to other studies describing outcomes
following AVR or MVR.2–8 In the present study, younger
patients who underwent bioprosthetic AVR were less likely
to be female, have preoperative atrial fibrillation, and un-
dergo concomitant CABG. Younger patients who underwent
MVR were also less likely to require concomitant CABG.

One of the main observations of this study was that
reoperation following bioprosthetic valve replacement is
influenced by patient age. Fifteen-year freedom from reop-
eration was 78% following AVR and 62% following MVR in
patients more than 60 years of age. In patients less than 40
years of age, 15-year freedom from reoperation was 54% and
36% following AVR and MVR, respectively. The median
interval to reoperation following AVR and MVR was not
established in patients more than 60 years of age, indicating
that at no point in time did 50% of the older patient cohort
undergo reoperation. Previous large cohort studies have also
confirmed the favorable freedom from reoperation following
bioprosthetic AVR with the Carpentier-Edwards, Hancock II,
Mosaic, and St. Jude Biocor, when implanted in patients more
than 65 years of age.6–8,14–15 A qualitative comparison of 10-
and 15-year freedom from reoperation following biopro-
sthetic AVR and MVR revealed that the freedom from reopera-
tion increases with patient age up to 70 years following AVR
and up to 75 years following MVR.

In this study, younger patients were more likely to undergo
reoperation, which is consistent with previously published
data. David et al showed in patients less than 60 years of age
who underwent AVR with the Hancock II prosthesis, the
20-year freedom from reoperation from any cause was
29.8±5.4%, and the median interval to reoperation was >17
years.5 Mykén and Bech-Hansen indicated that the 20-year
freedom from reoperation due to structural deterioration in
patients less than 65 years was 44.5±9.2% and 75.2±7.6%
following aortic or mitral valve replacement, respectively,
with the St. Jude Biocor.15 In patients less than 60 years of
age, we previously showed that reoperation occurred in 89%
and 84% following bioprosthetic AVR and MVR by 20 years,
respectively, and that long-term survival was not influenced
by prosthesis type.9 In patients between 45 and 65 years of
age, the 7-year freedom from reoperation for aortic valve
bioprostheses was 90±8%.21

Despite the above published data and the fact that biopros-
theses are increasingly used in younger patients across North
America,10–12 there had been only scarce reoperation data
available in younger patients. The present study provides this
information and allows for an evidence-based discussion for
young valve patients and the physicians treating them. We
also found that patients who required concomitant CABG at
the time of valve surgery were less likely to undergo
subsequent reoperation. This may be secondary to the nega-
tive impact of CABG on long-term survival following AVR
and MVR.18–19 After controlling for comorbidities, age re-
mained an important predictor of reoperation following bio-
prosthetic AVR and MVR. Each additional year of age at the
time of initial valve replacement was associated with a 6%
decrease in reoperation risk following bioprosthetic AVR and
with a 4% decrease in reoperation risk following bioprosthetic
MVR.

Reoperation following bioprosthetic valve replacement is
also influenced by valve type. Aortic valve allografts have
worse freedom from reoperation compared with stentless
valves.22 In turn, stentless valves may have worse freedom
from reoperation compared with stented xenografts. In a
prospective randomized trial, 12-year freedom from reopera-
tion was 92±5% with the Carpentier-Edwards pericardial
valve, compared with 75±5% with the Toronto SPV valve
(P=0.7).23 To minimize the potential for bias, the analyses of
longevity of bioprosthetic aortic valves in the present study
were restricted to stented bioprostheses. One of those, the
Ionescu-Shiley bioprosthetic valve, had been previously
shown to undergo early failure, with 10-year freedom from
reoperation of 57±4% and 61±6% following AVR and
MVR, respectively.24 In this study, the Ionescu-Shiley pro-
thesis was used in 16% of AVR and 29% of MVR; conse-
quently, the analyses were repeated with contemporary pros-
theses only, which excluded the Ionescu-Shiley valves.

Limitations

This was a nonrandomized study, and the decision to implant
a bioprosthesis was made between the patient and the
operating surgeon. The selection of a bioprosthesis may have

Table 4. Risk Factors Associated With Reoperation After
Bioprosthetic MVR

<table>
<thead>
<tr>
<th></th>
<th>Hazard Ratio</th>
<th>95% CI</th>
<th>P Value</th>
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<tbody>
<tr>
<td>Univariable*</td>
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<tr>
<td>Age (per increasing year)</td>
<td>0.95</td>
<td>0.94 to 0.97</td>
<td>&lt;0.001</td>
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<tr>
<td>Concomitant CABG†</td>
<td>0.42</td>
<td>0.24 to 0.71</td>
<td>0.001</td>
</tr>
<tr>
<td>Female gender</td>
<td>1.62</td>
<td>0.97 to 2.71</td>
<td>0.07</td>
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<tr>
<td>Preoperative atrial fibrillation‡</td>
<td>1.24</td>
<td>0.45 to 3.44</td>
<td>0.67</td>
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<tr>
<td>Preoperative ejection fraction ≤35%</td>
<td>1.28</td>
<td>0.27 to 6.02</td>
<td>0.75</td>
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<tr>
<td>Multivariable*</td>
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<tr>
<td>Age (per increasing year)</td>
<td>0.96</td>
<td>0.95 to 0.98</td>
<td>&lt;0.001</td>
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<tr>
<td>Concomitant CABG†</td>
<td>0.55</td>
<td>0.32 to 0.93</td>
<td>0.03</td>
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<tr>
<td>Female gender</td>
<td>1.28</td>
<td>0.76 to 2.15</td>
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CABG indicates coronary artery bypass grafting; MVR, mitral valve replacement.
*Model developed by incorporating contemporary bioprostheses only.
†Entered into model as a dichotomous variable.
‡Includes preoperative permanent and known paroxysmal atrial fibrillation.
been influenced by patient comorbidities. An attempt was made to determine the need for reoperation following bioprosthetic valve replacement while controlling for patient and operative factors; however, the possibility exists that unmeasured confounders may have influenced outcomes. The decision to undergo reoperation may also be influenced by patient comorbidities and technical factors, such as patent coronary artery bypass grafts, which may complicate reoperative surgery, thereby artificially bolstering the freedom from reoperation. Reoperation data pertaining to individual bioprosthesis models is not described, as further subanalysis are underpowered. Modes of prosthesis failure requiring reoperation, and also the influence of concomitant postoperative medical therapy, such as statins, are not described.

Conclusions
This study provides age-specific prognostic information regarding reoperation in patients undergoing AVR or MVR based on a large cohort of patients with detailed follow-up. These data add to the relatively scarce literature describing reoperation following bioprosthetic valve replacement in younger (<60 years) patients. These data may allow patients to make a more informed decision regarding prosthesis type at the time of initial surgery and allow physicians to better estimate their patients’ long-term outcomes.

Disclosures
Dr Ruel is on the speakers’ bureau of Medtronic. Dr Ruel also receives a research grant from Edwards Lifesciences.

References
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