

Results of Concomitant Aortic Valve Replacement and Coronary Artery Bypass Grafting in the VA Population

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Background and aim of the study: Concomitant aortic valve replacement (AVR) and coronary artery bypass grafting (CABG) is an established risk factor for diminished postoperative survival. Results from a VA population were reviewed in order to determine factors influencing early and late survival.

Methods: Between 1993 and 2003, a total of 401 patients underwent AVR at the authors' institution. Of these patients, 249 (62%; mean age 70.6 years) had combined AVR and CABG. Surgical indications were primarily aortic valve pathology (group A: n = 168; 68%), primarily coronary artery disease (CAD) (group B: n = 55; 22%), and both severe aortic and coronary disease (group C: n = 26; 10%). In total, 177 patients (71%) received a bioprosthesis, and 72 (29%) received a mechanical valve. Short- and long-term outcomes were explored using univariate and multivariable hazard analyses.

Results: Overall operative mortality was 6.4%; mortality for groups A, B and C was 4.8%, 9.1% and 11.5%, respectively. On multivariable analysis, significant factors associated with early-phase mortality

Aortic valve replacement (AVR) is the most common valve procedure performed in the United States, and more than 50% of patients undergoing AVR also require concomitant coronary artery bypass grafting (CABG). The combined procedure has been identified as a marker for increased operative mortality and diminished postoperative survival (1-4). However, individuals requiring concomitant AVR and CABG form a heterogeneous group of patients, and surgical outcomes vary within this group. Herein, the influence

were NYHA class IV, diabetes, bioprosthetic valve and combined severe aortic and coronary disease. Survival at one and five years was 86% and 62%, respectively. Five-year survival for groups A, B and C was 71%, 63% and 54%, respectively. Significant associated factors for late-phase mortality were the presence of preoperative peripheral vascular disease (PVD) and cerebrovascular disease (CVD). Factors such as age, prior cardiac surgery, number of grafted coronary arteries, and/or effective orifice area index (EOAI) had no significant effect on outcome.

Conclusion: Combined AVR/CABG is a marker for decreased survival. Pre-existing factors such as diabetes, PVD and CVD, as well as poor preoperative NYHA functional status, affected survival. Further investigation is needed to assess the influence of the severity of CAD and EOAI on survival. Thoughtful consideration of all these factors is essential for an accurate prediction of survival, and to determine the appropriate type of aortic prosthesis to be used.

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was studied of the primary cardiac pathology (defined as the symptomatic pathology requiring surgical intervention) on operative outcome. Factors associated with poor early and late survival were identified, and investigations made into the influence of factors previously reported to affect survival, such as patient age, number of CABGs, presence of patient-prosthesis mismatch (PPM) and type of prosthetic valve, in an attempt to provide patient-specific recommendations to help guide appropriate prosthetic valve selection.

Clinical material and methods

Patients

Between January 1993 and December 2003, a total of 401 sequential unselected patients underwent AVR at the Portland Veterans Affairs Medical Center. Of these patients, 249 (62%) underwent combined AVR/CABG. The clinical, operative and outcome data of these

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patients were reviewed. All operative and preoperative data were collected prospectively in a computerized database.

Inclusion criteria

Patients were allocated to three groups based on their primary cardiac pathology, defined as the symptomatic pathology requiring surgical intervention. Group A included 168 patients (68%) who required surgery predominantly for aortic valve pathology with associated angiographic findings of asymptomatic CAD. Group B comprised 55 patients (22%) requiring revascularization for significant CAD and with echocardiographic findings of associated asymptomatic aortic valve disease. Group C comprised 26 patients (10%) requiring surgery for both symptomatic severe aortic valve disease and CAD.

The clinical profiles of patients in the three groups are listed in Table I.

Follow up

Late outcomes were determined from the patients' clinical records. The Portland VAMC has a completely

computerized medical record system that covers both inpatient and outpatient visits. Survival records were determined from the VA database. The mean follow up was 3.17 ± 2.6 years, and was 100% complete for patient survival.

Surgical technique

All surgical procedures were carried out via a mid-line sternotomy. AVR was performed employing the usual techniques of cardiopulmonary bypass (CPB). Myocardial protection strategies included blood cardioplegia with mild hypothermia. Retrograde cardioplegia introduced through a coronary sinus cannula was used in some patients. The core temperature was lowered to 30-32°. Distal coronary anastomoses were performed first, followed by AVR and, finally, the proximal coronary anastomoses. Selection of the aortic valve prosthesis was based on the patient's age, expected survival, and the surgeon's preference. Intraoperative transesophageal echocardiography was used in almost all cases during the past eight years. All procedures were performed by cardiac residents as the primary surgeons. The operative data are summarized

Table I: Clinical profile of the three patient groups. Values expressed as % of patient group (unless otherwise indicated)

| Parameter | Group A | Group B | Group C |
|-----------------------------------|------------|------------|------------|
| No. of patients | 168 | 55 | 26 |
| Age (years)* | 70.6 ± 7.5 | 70.6 ± 7.0 | 71.1 ± 8.6 |
| NYHA class | | | |
| I | 15 | 20 | 15 |
| II | 20 | 31 | 19 |
| III | 45 | 40 | 54 |
| IV | 20 | 9 | 12 |
| CCS class | | | |
| I | 18 | 2 | 4 |
| II | 20 | 7 | 15 |
| III | 49 | 60 | 42 |
| IV | 14 | 31 | 39 |
| Previous cardiac surgery | 14 | 6 | 27 |
| Comorbidities | | | |
| Diabetes | 11 | 69 | 62 |
| COLD | 38 | 29 | 11 |
| CVD | 40 | 35 | 27 |
| PVD | 25 | 14 | 35 |
| LVEF | | | |
| >55% | 56 | 53 | 47 |
| 35-55% | 39 | 46 | 53 |
| <35% | 5 | 0 | 0 |
| No. of stenotic coronary arteries | | | |
| 1 | 36 | 7 | 0 |
| 2 | 41 | 38 | 19 |
| 3 | 23 | 55 | 81 |

*Values are mean ± SD.

CAD: coronary artery disease; CCS: Canadian Cardiovascular Society classification; COLD: Chronic obstructive lung disease; CVD: Cerebrovascular disease; LVEF: Left ventricular ejection fraction; PVD: Peripheral vascular disease.

in Table II.

Statistical analysis

All data analyses were performed using SAS statistical software (version 9; SAS Institute, Inc., Cary, NC, USA). Data were presented as frequency, median (with range) or mean (\pm SD) as appropriate, with the number of non-missing values indicated. Non-informative imputation based on available data was used to calculate and place the mean for missing values. Relevant missing value indicator variables were created and included in multivariable analyses to adjust for possible bias introduced by missing data. Risk-unadjusted freedom from time-related death was estimated non-parametrically using the Kaplan-Meier method. Multiphase parametric modeling of the underlying hazard-function was then used to search for discrete phases of risk. Demographic, morphologic and procedural factors associated with each outcome were sought using multivariable regression of the hazard models. Only variables associated with more than five events were included to minimize the risk of model over-determination. Mathematic transformations were tested to optimize calibration, and the significance of various interaction terms was explored. Bootstrap bagging with cluster analysis was used to guide final vari-

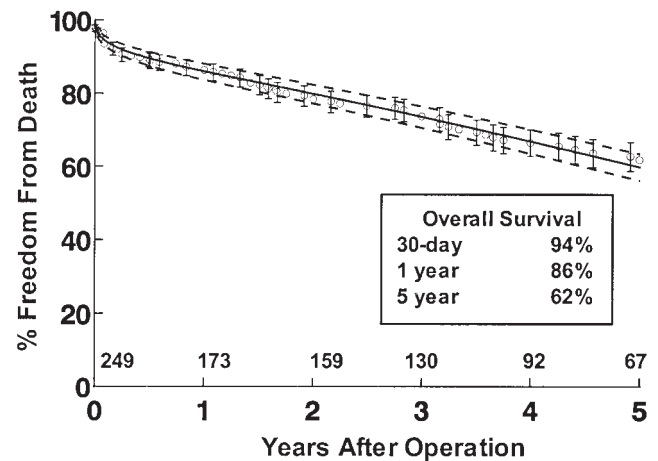


Figure 1: Overall time-related survival of 249 patients following combined aortic valve replacement and coronary artery bypass grafting. The hazard function for death is characterized by an early phase predominating until just after one year, accounting for 49 events, and a prolonged late phase predominating thereafter, accounting for 43 events.

able selection and to assess reliability of variable inclusion into final multivariable models.

Table II: Operative data.

| Parameter | No. of events |
|--|-----------------|
| No. of patients | 249 |
| Surgical urgency | |
| Elective | 228 (92) |
| Urgent | 16 (6) |
| Emergent | 5 (2) |
| CPB time (min)* | 209 \pm 49 |
| Aortic cross-clamp time (min)* | 131 \pm 36 |
| Valve type | |
| Tissue | 177 (71) |
| Mechanical | 72 (29) |
| EOAI (cm ² /m ²)* | 0.88 \pm 0.19 |
| EOAI (cm ² /m ²) | |
| >0.85 | 112 (45) |
| 0.66-0.85 | 125 (50) |
| \leq 0.65 | 12 (5) |
| No. of bypass grafts | |
| 1 | 67 (27) |
| 2 | 74 (30) |
| 3 | 66 (26.5) |
| 4 | 38 (15) |
| 5 | 4 (1.6) |
| Mitral valve replacement | 7 (2.8) |

*Values are mean \pm SD.

Values in parentheses are percentages.

CPB: Cardiopulmonary bypass; EOAI: Effective orifice area index.

Results

The 30-day mortality was 6.4% (n = 16), with mortality for groups A, B and C being 4.8%, 9.1% and 11.5%, respectively. Postoperative complications included ventilator support exceeding 48 h in 26 patients (10.5%), re-exploration for bleeding in 15 (6%), stroke in 11 (4.4%), perioperative myocardial infarction in three (1.2%), and renal failure in two (0.8%).

The one- and five-year survivals were 86% and 62%, respectively (Fig. 1). The hazard for mortality was characterized by an early hazard phase terminating at one year, and a late hazard phase which predominated thereafter (Fig. 1). Multivariable incremental risk factors associated with increased early-phase mortality included preoperative NYHA class IV, diabetes, severe combined aortic and coronary artery disease, and the use of a bioprosthetic valve (Table III).

Associated risk factors for late-phase mortality were the presence of preoperative peripheral vascular disease (PVD) and cerebrovascular disease (CVD) (Table III).

Impact of surgical pathology

The five-year risk-unadjusted survival for patients undergoing AVR and CABG for primary aortic pathology was 71%, while patients with predominant coronary artery pathology had a five-year survival of 63%, and those with both severe aortic and coronary artery pathology had a five-year survival of 54% (Fig. 2).

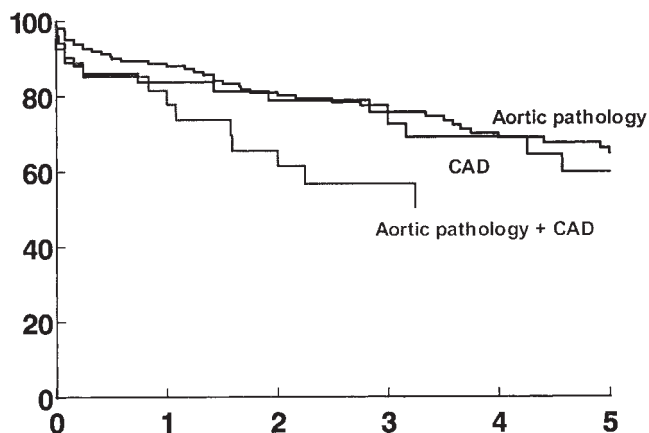


Figure 2: Overall risk-unadjusted mortality stratified by predominant type of initial presenting pathology. CAD: Coronary artery disease.

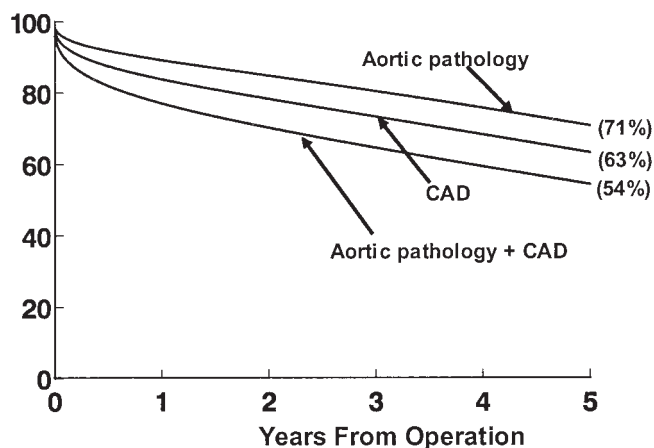


Figure 3: Risk-adjusted predicted survival for a hypothetical patient with favorable characteristics stratified by the predominant initial pathology. Mortality is significantly increased in the group with combined aortic and coronary pathology ($p < 0.001$ from initial model).

Using the parametric multivariable model, three different solutions to the multivariable equation were derived for a patient in each group, showing that the five-year risk-adjusted survival remains significantly lower in patients with combined pathology after adjustment for all other significant predictors (Fig. 3). However, the difference in survival was mainly related to the higher early-phase mortality rate of patients with severe combined disease, with the curves becoming almost parallel beyond one year postoperatively.

Impact of number of coronary artery grafts

The number of coronary artery bypass grafts performed did not correlate with early- or late-phase survival in the present series. In fact, those patients who received three grafts or more showed a small trend towards increased survival (Fig. 4). On multivariable analysis, the impact of the number of grafts did not reach statistical significance ($p = 0.6$).

Impact of aortic prosthesis size

In order to determine whether implantation of a small prosthesis causing PPM would affect survival, patients were allocated to subgroups having either no PPM ($n = 112$; 45%), moderate PPM ($n = 125$; 50%) or severe PPM ($n = 12$; 5%). Survival data are illustrated graphically in Figure 5. Although there might have been a trend towards decreased survival in the presence of PPM, statistical significance was not reached.

Impact of aortic prosthesis type

As mentioned previously, bioprosthetic valve use was associated with increased early-phase mortality. However, the magnitude of survival difference was small and confined mainly to the early postoperative period (Fig. 6).

Impact of other factors

Patient age did not influence either early- or late-phase survival. In addition, comparison between

Table III: Incremental risk factors for time-related death after initial operation.

| Variable | Coefficient (±SE) | p-value | Reliability (%) |
|---------------------------------|-------------------|---------|-----------------|
| Early-phase mortality (n = 47) | | | |
| Preoperative diabetes | 0.90 ± 0.34 | 0.009 | 89 |
| Preoperative NYHA class IV | 0.87 ± 0.37 | 0.02 | 73 |
| Tissue prosthesis implant | 1.92 ± 0.82 | 0.01 | 73 |
| Combined aortic pathology + CAD | 0.86 ± 0.41 | 0.04 | 80 |
| Late-phase mortality (n = 43) | | | |
| Preoperative CVD | 0.89 ± 0.33 | 0.007 | 88 |
| Preoperative PVD | 0.57 ± 0.34 | 0.09 | 54 |

CAD: Coronary artery disease; CVD: Cerebrovascular disease; PVD: Peripheral vascular disease.

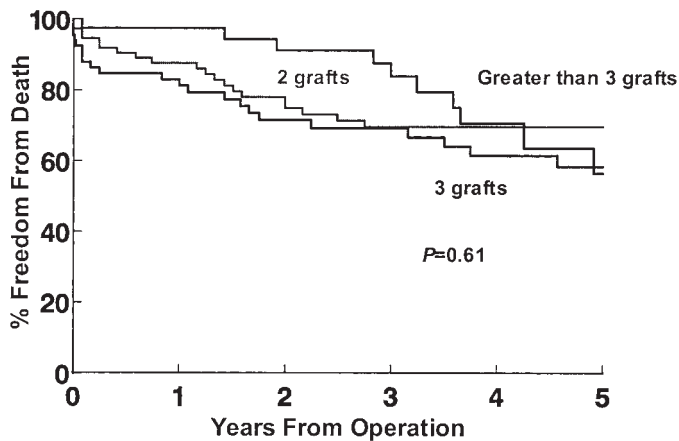


Figure 4: Risk-unadjusted (Kaplan-Meier) plot stratified by number of bypass grafts.

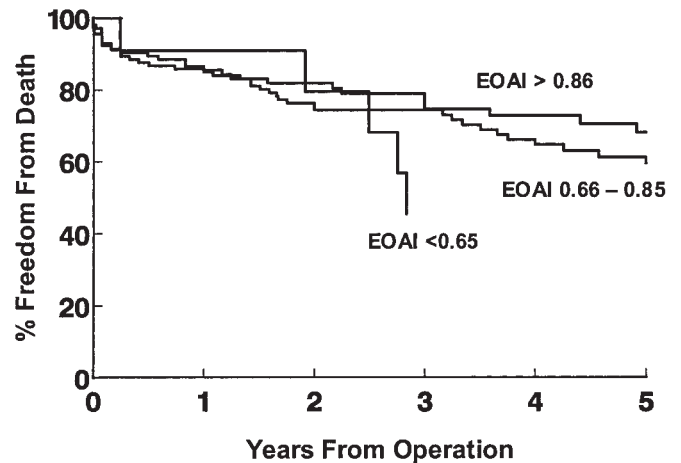


Figure 5: Overall risk-unadjusted mortality stratified by effective orifice area index (EOAI) category.

patients aged <65 years and >65 years showed no statistical significance ($p = 0.13$). Preoperative NYHA functional class was shown to influence mortality, but this was confined to early-phase rather than to late-phase survival.

Other factors such as CPB duration or cross-clamp time, mode of administration of cardioplegia, surgical urgency and prior cardiac surgery were not significant factors in either early- or late-phase mortality.

Discussion

Aortic valve replacement is the most frequently performed valve procedure in the United States. Indeed, since 1996, and based on the Society of Thoracic Surgeons (STS) national database, the number of combined AVR and CABG procedures each year has exceeded the number of isolated AVR procedures. Among STS national database participants, combined AVR and CABG carried a higher mortality rate compared to isolated AVR or CABG alone (6.2%, 3.8% and 2.6%, respectively) (5). This finding may be related to the longer, more complex surgery required as well to the increased age, comorbid conditions and incidence of ventricular dysfunction in patients with combined disease. Several reports have also indicated that a combined AVR and CABG procedure is associated with reduced long-term survival compared to isolated AVR (1-4).

Indications for the combined procedure vary between patients. The first group includes those patients who require AVR for symptomatic aortic valve pathology, and in whom preoperative coronary angiography detected coexisting coronary lesions. CABG is then performed to avoid perioperative ischemic events, and to reduce the risk of future coronary re-intervention. Several reports have suggested

that CABG might offer some survival advantage in this group of patients by reducing the incidence of late coronary events and sudden death (6,7). The second group of patients includes those who require surgery for CAD, their preoperative echocardiogram having revealed coexisting asymptomatic aortic valve disease. Based on the AHA/ACC recommendations, AVR is indicated in patients with moderate or severe aortic stenosis or regurgitation undergoing CABG (8). Controversy persists, however, in the management of mild aortic stenosis at the time of CABG. Proponents of the combined approach argue that 'prophylactic AVR' avoids the morbidity of a second operation, without adding a significant operative mortality risk, whereas redo AVR after CABG is associated with significant morbidity and mortality (9,10). Meanwhile, opponents contend that performing AVR at the time of

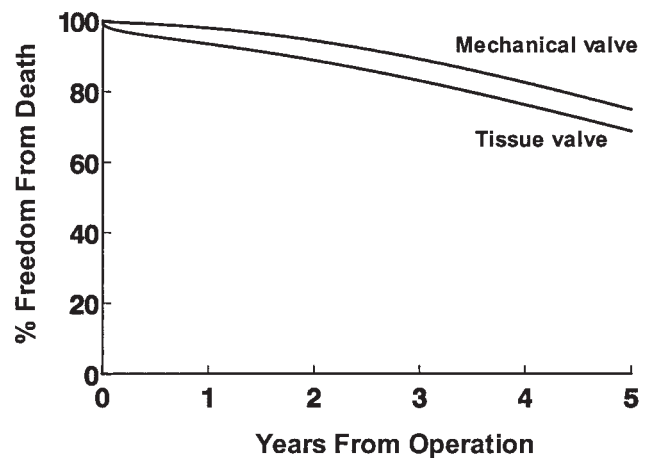


Figure 6: Risk-adjusted predicted survival for a hypothetical patient with favorable characteristics stratified by type of aortic valve prosthesis. Mortality is significantly increased in patients receiving tissue valves compared to those with mechanical valves ($p < 0.02$).

CABG will increase operative risk, subject patients to the complications of a prosthetic valve and the possibility of structural valve deterioration without eliminating the chance of reoperation, and that redo AVR after previous CABG can be performed safely when needed (11,12). Given current surgical results, most surgeons agree that AVR is indicated at the time of CABG in those patients expected to have good medium- to long-term survival and in whom the aortic valve gradient exceeds 25 mmHg, especially when excessive calcification or immobility of the aortic valve leaflets is present (9). The final group of patients includes those with severe CAD and aortic valve disease. Here, the clinical picture is often complex as symptoms such as angina and congestive heart failure may be explained by either etiology. In addition, these patients are usually older, have a high incidence of associated ventricular dysfunction, and are more likely to have poor short-term and long-term outcomes. Patients with combined severe disease had higher early-phase mortality in the present series. Complete coronary revascularization and AVR, allowing left ventricular mass regression and improvement in left ventricular dysfunction rendered the actuarial survival of patients with severe combined disease and that of patients who underwent combined AVR and CABG for isolated aortic or coronary indication identical.

Taking these facts into consideration is essential when selecting the prosthetic aortic valve to be implanted. Given the diminished survival of patients undergoing combined AVR and CABG, some investigators have advocated lowering the age threshold for using bioprostheses for AVR in patients who require concomitant CABG (13). The majority of patients with severe aortic valve disease and CAD will not live long enough to experience structural valve deterioration. In a retrospective review by Akins et al. of 750 patients who underwent combined AVR and CABG, valve type was not predictive of late mortality. However, mechanical AVR was associated with worse survival compared with predicted and more valve-related complications due to anticoagulation requirements (4). The findings of Akins et al. may be attributed to the fact that patients receiving mechanical valves were younger and their predicted survival was higher; therefore, the difference between their observed and predicted survival was more pronounced. Nonetheless, these results validated findings by previous reports that bioprosthetic valves might be preferable in younger patients requiring CABG at the time of AVR (3,13-15). In the present study, it could be argued that patients undergoing AVR and CABG are heterogeneous, and that their survival would be greatly influenced by the extent of their CAD, comorbid conditions, and the amount of ventricular dysfunction. None of those factors should be viewed in

isolation. The finding in the present study that bioprosthetic implantation was associated with decreased survival was most likely due to an association between this variable and other unmeasured, or unidentified, covariables. Patients having mechanical valves were likely younger and had an improved NYHA functional status than those receiving tissue valves. Although interactions between variables were considered, the present study was not of sufficient power to evaluate all possible co-relationships. It is unlikely, that the bioprosthetic valve itself is related to any increase in operative mortality.

Another controversial issue when making valve selection is that of PPM, defined as an effective orifice area index (EOAI) value $<0.85 \text{ cm}^2/\text{m}^2$. The presence of PPM following AVR would subject the patients to persistent abnormally high gradients, with decreased left ventricular mass regression and potential impact on early and late surgical outcomes (16,17). Several reports have suggested that the existence of PPM after AVR is associated with increases in postoperative early mortality (18), congestive heart failure (19), valve-related long-term mortality (20), and diminished overall survival (21). In the present series, the incidence of PPM was 55%, with 5% of patients having severe PPM with EOAI $<0.65 \text{ cm}^2/\text{m}^2$. Although there was a trend in this series for diminished survival in patients with PPM, the difference was not statistically significant. Several annular- and root-enlarging procedures can be performed to enable upsizing of the valve prosthesis. However, that may increase the complexity of the surgery, and subject the patients to prolonged CPB and aortic occlusion times. In addition, the current presence of a new generation of aortic valve prostheses, may reduce the number of patients having PPM. Nonetheless, further studies are needed to identify the subset of patients most affected by PPM, and every effort should be made to avoid placement of small prostheses in this subgroup of patients. It is likely that younger patients, those with larger body size, and longer expected survival are the most likely to benefit from surgical methods that ensure adequate matching between the patient's body size and the aortic valve prosthesis, including annulus-enlarging procedures, the choice of stentless valves or aortic root replacement.

In conclusion, those individuals requiring concomitant AVR and CABG constitute an heterogeneous group of patients based on the cardiac pathology requiring surgery, the magnitude of their CAD, comorbid conditions, and the degree of ventricular dysfunction. Each patient's treatment should be individualized, and thoughtful consideration of all factors during AVR is essential when considering the type of valve to be implanted.

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Meeting discussion

DR. WILHELM MISTIAEN (Antwerp, Belgium): Were many patients operated on under urgent conditions?

DR. BAHAAALDIN ALSOUFI (Toronto, Ontario, Canada): Only about 7% were operated on in an emergency, and that factor was not significant on univariate analysis.

DR. MISTIAEN: Could the duration of cross-clamp time have any influence on survival?

DR. ALSOUFI: We considered it as having 20-minute increments, and it was not a factor.

DR. MISTIAEN: You showed that the implantation of a biological valve was a significant factor.

DR. ALSOUFI: Yes, it was significant for the early phase of mortality. I don't think it is related to the biological valve itself - it's related to the fact that there are so many covariables that will interact with this variable and these were not tested in our series. Our study did not have the power to detect those variables. We tried to adjust for age and other comorbidities, and that continued to be a significant factor.

DR. MISTIAEN: Was age a criterion for implanting a pericardial or a biological valve?

DR. ALSOUFI: There was no clear criterion. About 70% of the patients had bioprostheses. As a retrospective study, the younger patients probably received the mechanical valves, but there was a significant number of young patients who were implanted with a bioprosthesis.

DR. MISTIAEN: So you can't say that the effect of the bioprosthesis was age-dependent?

DR. ALSOUFI: Age was not a factor, even on univariate analysis. The risk-adjusted survival for the bioprosthesis, taking age into account, showed that the bioprosthesis was a significant factor for early hazard.

DR. GAETANO THIENE (Padova, Italy): When you refer to the choice of prosthetic aortic valve, are you referring to the stentless valve, because the cross-clamp time is much longer and there may be myocardial injury? In other words, if you have concomitant aortic and coronary valve disease, would it be better

not to use the stentless because it takes more time for cross-clamping?

DR. ALSOUFI: Probably. But only two stentless valves were used in this study. This is a teaching hospital, and as all procedures were carried out by residents the cross-clamp time was probably longer than would be expected. But cross-clamp time was not a significant factor in the analysis. Your opinion is valid that we should limit the bypass and cross-clamp times in those patients with an already long cross-clamp time, but it was not a significant factor.

DR. THIENE: You concluded that these factors could have an implication on the type of prosthesis implanted. What do you mean?

DR. ALSOUFI: I mean that by identifying certain factors you can predict survival better. Those patients expected to have good survival because they don't have all the risk factors are probably those who would be given a mechanical prosthesis. Knowing more about the risk factors would help you to predict the survival of those patients.

DR. THIENE: Regardless of whether a stented or unstented valve was used - or even a biological valve?

DR. ALSOUFI: Yes - you simply choose. It's probably not a bad idea in a 40-year-old patient with all good factors and single-vessel disease to offer a Ross procedure if you think their survival is going to be good. You need to know how to estimate survival in those patients, because they are heterogeneous.