doi:10.1510/icvts.2008.193482

INTERACTIVE CARDIOVASCULAR AND THORACIC SURGERY

Interactive CardioVascular and Thoracic Surgery xxx (xxx) xxx–xxx

www.icvts.org

Institutional report - Valves

Long-term follow-up of elderly patients subjected to aortic valve replacement with mechanical prostheses☆

Gonçalo F. Coutinho, Rita Pancas, Pedro E. Antunes, Manuel J. Antunes*

Centre of Cardiothoracic Surgery, University Hospital, Coimbra, Portugal

Received 5 September 2008; received in revised form 27 April 2009; accepted 29 April 2009

Abstract

We propose to analyse the long-term follow-up in patients older than 65 years of age who received a mechanical valve in the aortic position, using death and prosthetic-related complications as endpoints. From April 1988 to December 1995, 144 consecutive patients 65–75 years of age (mean 67.7±2.5) were enrolled. Total duration of follow-up was 1663 patient-years (median 13.0 years) and was complete for 99% of the patients. Thirty-day mortality was 1.4% (n=2). At the end of the study, 77 patients (53.8%) were alive, with ages ranging from 77 to 91 years (mean 82.1±3.2 years). The overall 5-, 10- and 15-year actuarial survival was 87.4%±3.0, 67.7%±4.3 and 58.5%±4.5, respectively. Freedom from stroke was 93.3±3.1%, 84.6±3.3% and 71.7±4.5%, respectively, after identical periods. Freedom from major bleeding was 97.2±1.1%, 90.4±3.5% and 86.4±4.0%, respectively. Freedom from endocarditis was 95.7±2.3%, 95.0±2.1% and 94.4±2.5%, respectively, and freedom from reoperation was 98.0±1.2%, 97.6±1.3%, 96.9±2.4% and 96.4±2.6%, respectively. Freedom from major valve-related events was 87.7±2.6%, 73.9±3.4% and 61.5±4.6%, respectively. Nearly two-thirds of the patients were alive and free from major adverse valve-related events. Hence, we consider implantation of a mechanical prosthesis in elderly patients safe and appropriate, but the choice must be tailored for each specific patient.

Keywords: Aortic valve replacement; Elderly; Mechanical prostheses; Bioprostheses

1. Introduction

There is no perfect valve substitute. All prostheses, whether mechanical or biological, involve some compromise and all introduce a new disease process, the prosthetic disease. Considerations for choosing between a mechanical valve and a bioprosthesis concern haemodynamic performance, long-term durability and the need for chronic anticoagulation.

Currently in Europe and in the USA, there are trends towards increasing the use of tissue valves, in progressively younger patients [1–3], probably supported by reports of very low rates of bioprosthetic failure in elderly patients [4, 5], particularly with the newer models [6].

Although there are several studies addressing the behaviour of mechanical valves in the elderly patients, only a few have long follow-up analysis concerning survival and valve-related events [7–10]. In the present study, we analyse early and late survival, adverse valve-related events and the quality of life in this specific patient population (65–75 years), in a follow-up of up to 20 years.

2. Material and methods

2.1. Patient population

From April 1988 to December 1995, a total of 144 consecutive patients aged 65–75 years (mean 67.7±2.5 years), 93 female (64.6%), underwent aortic valve replacement (AVR) with a mechanical prosthesis. Patients receiving concomitant coronary artery bypass surgery (CABG) and other surgical procedures were included. The time interval for inclusion in this study was determined to permit at least a 12-year period of follow-up.

During the same time interval, we also implanted 102 bioprostheses in patients of this age group. The initial design of the work was a comparative study between the two types of valves, but patients in the biological valve group were significantly older, with more co-morbidities, which precluded an accurate comparison.

Preoperatively, 87 patients (60.4%) were in NYHA (New York Heart Association) class III or IV, 28 (19.4%) had left ventricular dysfunction (ejection fraction <45%) and 30 (20.8%) were in chronic atrial fibrillation. Table 1 summarizes the baseline demographic and clinical characteristics of the patients.

Surgical indications for AVR were: stenosis (n=101, 70.1%), insufficiency (n=40, 27.8%) and endocarditis (n=3, 2.1%), including one case of aortic prosthetic endocarditis. Five cases were re-operative cardiac interventions (3.5%).

☆ Presented at the 22nd Annual Meeting of the European Association for Cardio-thoracic Surgery, Lisbon, Portugal, September 14–17, 2008.

*Corresponding author. Centro de Cirurgia Cardiotorácica, Hospitais da Universidade, 3000-075 Coimbra, Portugal. Tel.: +351-239400418; fax: +351-239829674.

E-mail address: antunes.cct.huc@sapo.pt (M.J. Antunes).

Table 1
Characteristics of the study population

Demographical/Clinical	*n* (%) or mean ± S.D.
Age (years, mean)	67.7 ± 2.5
Sex (female)	51 (35.4%)
Body surface area (m^2)	1.72 ± 0.74
NYHA class III–IV	87 (60.4%)
LV dysfunction (EF < 45%)	28 (19.4%)
Valve pathology (predominant lesion)	
Insufficiency	40 (27.8%)
Stenosis	101 (71%)
Endocarditis	3 (2.1%)
Chronic atrial fibrillation	30 (20.8%)
Previous cardiac surgery	5 (3.5%)
Surgery	
ECC time (min)	84.4 ± 12.7
Aortic cross-clamping (min)	54.8 ± 12.7
Aortic cross-clamping time (min)	54.8 ± 12.7
Associated procedures	
CABG	16 (11.1%)
Mitral valve repair	14 (9.7%)
Reduction ascending aortoplasty	3 (2.1%)
Mitral valve replacement	3 (2.1%)
Mitral and tricuspid valve repair	2 (1.4%)
Ascending aorta replacement	1 (0.7%)

NYHA, New York Heart Association; EF, ejection fraction; ECC, extracorporeal circulation; CABG, coronary artery bypass grafting.

The decision to implant a mechanical valve was made jointly by the cardiac surgeon, cardiologist, nurse and patient. Performance status, physical condition, ability to manage anticoagulation (including good family support) and patient's tolerance to the eventual need for repeat valve replacement were our main determinants of valve selection.

2.2. Operative technique and data

The operative technique was standardized for all patients and included cardiopulmonary bypass with moderate hypothermia (28–30°), topical cooling with ice slush in the pericardium and intermittent antegrade cold crystalloid cardioplegia, either in the aortic root or directly in the coronary ostia.

Only two types of aortic prostheses were implanted, Medtronic-Hall (Medtronic Inc, Minneapolis, MN, USA) and Carbomedics (Sulzer Medica, Austin, TX, USA), both considered to have low thrombogenicity [11].

Concomitant procedures were performed in 39 patients (27%), the most frequent being CABG and mitral valve repair (Table 1).

2.3. Anticoagulant management

Anticoagulation was initiated with warfarin on the first or second postoperative day, depending on the patient's condition. During the initial years of this experience, the prothrombin time or index were used to monitor the level of anticoagulation, with a target prothrombin time ratio of 1.5–2. More recently, the international normalized ratio (INR) has been used to monitor the level of anticoagulation with a target of 2.0–3.0 units. Control of the prothrombin time or the INR after discharge from the hospital was done by the patient's physician, after initial stabilization by the surgeons (all patients had a blood sample drawn for anticoagulation control at the time of the last postoperative visit, usually at 1 month).

2.4. Data collection, follow-up and outcome events

Perioperative data were obtained by review of the patient's hospital records, catheterization reports, cineangiograms and echocardiography. Follow-up information was collected during a 3-month period (cross-sectional mode), closing end of January 2008. This was done through a mailed questionnaire or by telephone interview with surviving patients, family members or the patient's physician. Follow-up data included information about activity level, current symptoms, occurrence of late cardiac and non-cardiac events, regularity of anticoagulation control and if the INR value was in the target range.

The total duration of follow-up for the entire cohort was 1663 patient-years (range 0–19.1 years, median 13.0 years (interquartile range 9.1–14.6 years) and was complete for 99% of the patients (one patient lost for follow-up).

Prosthetic-related complications were recorded according to the 2008 Guidelines for Reporting Mortality and Morbidity after Cardiac Valve Interventions [12]. Major adverse valve-related events (MAVE) included: valve-related mortality (sudden, unexplained death included); all valve-related morbidity and need for new permanent pacemaker or defibrillator within 14 days after the valve intervention.

2.5. Statistical analysis

Data were presented as frequency distributions and simple percentages. Continuous variables were expressed as mean ± standard deviation (S.D.). Patient survival was calculated by actuarial analysis according to the Kaplan–Meier method, using time zero as the date of operation and late death as the end point (with variability expressed as standard error of mean). Linearised rates of occurrence for selected events were calculated and expressed as % per patient-year (pt-yr). Data were analysed using the SPSS software package (SPSS, Inc, Chicago, Illinois, USA).

3. Results

3.1. Hospital mortality and morbidity

There was only one hospital death (0.7%), due to aortic rupture in the first postoperative day. The patient was reopened in extremis in the ICU, but it was not possible to control the bleeding. One patient died from sudden death two weeks after discharge (30-day mortality, 1.4%).

One-third of the patients (33.3%), experienced some type of postoperative morbidity, the most frequent being rhythm disturbances (atrial fibrillation/flutter, complete AV block), followed by acute renal failure (creatinine > 2 mg/dl) and respiratory complications (infectious, pneumothorax, pleural effusion) (Table 2). Most episodes were minor and easily controlled.

The mean length of hospital stay was 9 ± 2.1 days.

Table 2
Causes of hospital morbidity

Complication	*n* (%)
Rhythm disturbances	23 (16.0)
Atrial fibrillation/flutter	20 (13.9)
Complete AV block	3 (2.1)
Acute renal failure	7 (4.9)
Respiratory complications	5 (3.5)
Reoperation (bleeding/tamponade)	5 (3.5)
CVA/TIA	3 (2.1)
Others	5 (3.5)

CVA, cerebro-vascular accident; TIA, transient ischemic attack.

Table 3
Causes of late death

Causes of death	*n* (%)
Cardiac mortality (non-valve related)	31 (46.9)
Heart failure	12 (18.12)
Acute myocardial infarction	3 (4.5)
Arrhythmias	2 (3.0)
Valve-related mortality	14 (21.2)
CVA	7 (10.6)
Prosthetic endocarditis	3 (4.5)
Sudden or unexplained death	3 (4.5)
Bleeding event	1 (1.5)
Non-cardiac mortality	30 (45.5)
Malignancy	10 (15.1)
Pulmonary causes	8 (12.1)
Head trauma	4 (6.0)
Car accident	3 (4.5)
Sepsis	2 (3.0)
Others	3 (4.5)
Unknown	5 (7.6)

CVA, cerebro-vascular accident.

3.2. Late mortality

During the course of this 20-year study, 66 patients died (45.8%). Nearly half of the deaths were non-cardiac, malignancies representing a major cause. There were 31 cardiac deaths (46.9%) and only 14 of those were valve-related (21.2%). Stroke was the most frequent cause of valve-related mortality, followed by prosthetic endocarditis and sudden death. The causes of late death are listed in Table 3.

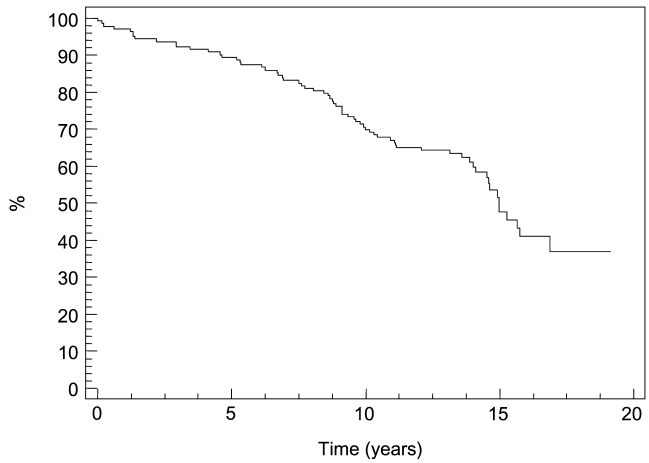
At the completion of this study, 77 patients (53.8%) were alive, with ages ranging from 77 to 91 years (mean 82.1±3.2 years).

Fig. 1 displays the long-term actuarial survival of the patients. The overall 1-, 5-, 10- and 15-year actuarial survival was 95.1%±2.1, 87.4%±3.0, 67.7%±4.3 and 58.5%±4.5, respectively. When the study population was subdivided in subgroups by age (65–69 years vs. 70–75 years), or according to associated procedures performed, there were no statistical differences regarding overall survival.

3.3. Valve-related events

3.3.1. Thromboembolism and major bleeding

Twenty-six patients (18.0%) experienced a neurological event (CVA/TIA), which was fatal in seven. Five patients who survived a stroke episode remained with some degree of disability, the others recovered fully. Two patients had more than one episode of thromboembolism. One-, 5-, 10- and 15-year freedom from stroke (Fig. 2) was 96.1±2.2%, 93.3±3.1%, 84.6±3.3% and 71.7±4.5%, respectively. The linearised incidence was 1.56%/pt-yr.



Years	1	5	10	15
Patients at risk	139	128	100	23

Fig. 1. Kaplan–Meier survival curve.

Fourteen patients (9.7%) suffered a major haemorrhage and one patient died from a spontaneous acute subdural haematoma. One-, 5-, 10- and 15-year freedom from major bleeding was 99.1±1.2%, 97.2±1.1%, 90.4±3.5% and 86.4±4.0%, respectively (Fig. 2). The rate of occurrence was 0.84%/pt-yr.

The linearised incidence of the composite outcome thromboembolism plus major bleeding was 2.4%/pt-yr.

3.3.2. Endocarditis and reoperation

Eight patients (5.5%) had prosthetic endocarditis, three underwent surgery and the remaining were treated medically. Three patients died from the event.

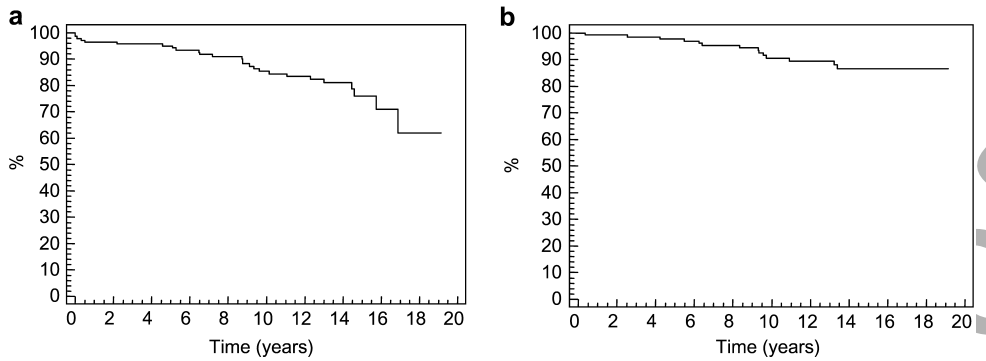
Five patients (3.5%) were subjected to at least one reintervention, three because of prosthetic endocarditis, one for paravalvular leak and one for nonstructural dysfunction (entrapment by pannus). Two patients had more than one reoperation (endocarditis).

One-, 5-, 10- and 15-year freedom from endocarditis was 96.4±1.6%, 95.7±2.3%, 95.0±2.1% and 94.4±2.5%, respectively (Fig. 3a), and freedom from reoperation was 98.0±1.2%, 97.6±1.3%, 96.9±2.4% and 96.4±2.6%, respectively (Fig. 3b). The linearised incidences of endocarditis and reoperation were 0.48%/pt-yr and 0.3%/pt-yr, respectively.

3.3.3. Major adverse valve-related events (MAVE)

Forty-one patients (28.5%) experienced at least one important adverse valve-related event. In 14 patients, it resulted in death, which means that nearly two-thirds of the patients outlived the adverse event.

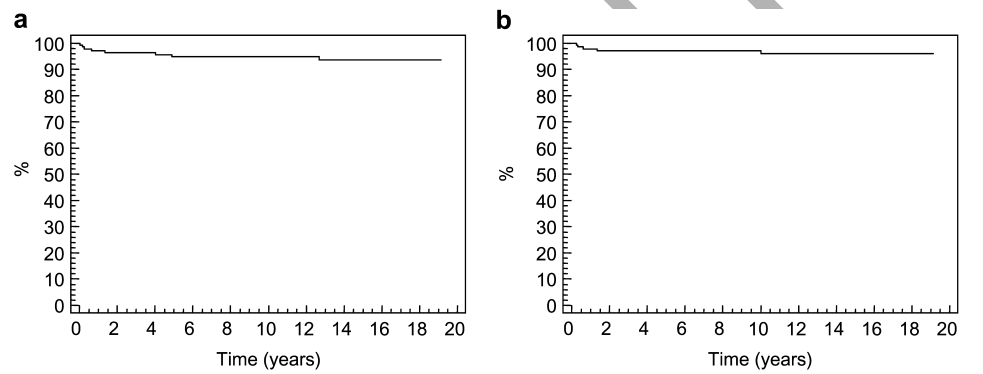
One-, 5-, 10- and 15-year freedom from MAVE was 92.8±1.0%, 87.7±2.6%, 73.9±3.4% and 61.5±4.6%, respectively (Fig. 4). MAVE occurred at a linearised rate of 2.5%/pt-yr.



Years	1	5	10	15
Patients at risk	134	123	89	19

Years	1	5	10	15
Patients at risk	138	125	89	20

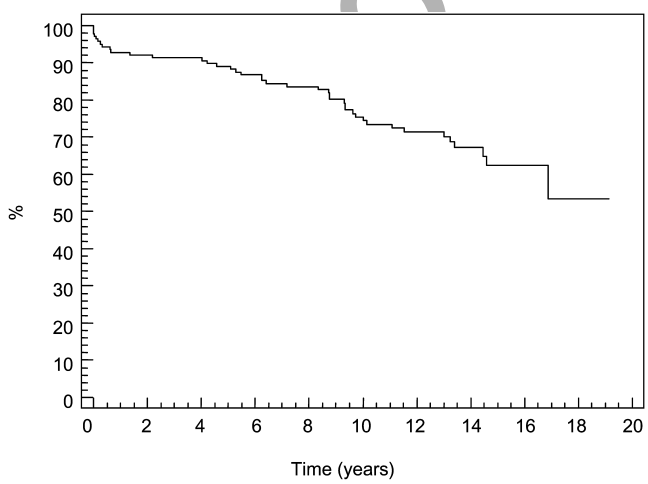
Fig. 2. Freedom from (a) thromboembolism; and (b) major bleeding.



Years	1	5	10	15
Patients at risk	136	124	97	20

Years	1	5	10	15
Patients at risk	136	126	99	22

Fig. 3. Freedom from (a) endocarditis; and (b) reoperation.



Years	1	5	10	15
Patients at risk	127	117	79	15

Fig. 4. Freedom from MAVE.

4. Discussion

Our policy regarding AVR is to implant a mechanical prosthesis in every 'suitable' patient until 70–72 years of age. The 'suitability' is determined by a comprehensive conversation, firstly with the cardiologist and nurse who received the patient and secondly with the cardiac surgeon, with the patient.

One particularity of this study is the long follow-up for this patient population, with a mean follow-up time of 11.7 ± 4.3 years and maximum of 19.1 years. At the completion of this study more than half of the patients were alive, with ages ranging from 77 to 91 years (mean 82.1 ± 3.2), which probably would have placed some of them at risk of reoperation for structural valve deterioration, if a bioprosthesis had been implanted.

The overall 10- and 15-year actuarial survival of our patients was 67.7% and 58.5%, respectively, which is, in our opinion, remarkable for this specific patient population. It is important to emphasize that only half of the late deaths were from cardiac causes and only about one-fifth were valve-related, including three sudden/unexplained deaths, meaning that freedom from cardiac and valve-related mortality was significantly better than the overall survival observed. There was no significant difference when comparing the overall survival of this cohort of patients to the life expectancy of the general population above

65 years of age (Institute of National Statistics; 16.9 vs. 17.9 years).

The fact that 18% of the patients suffered from at least one episode of thromboembolism would appear to be a high risk, but the linearised incidence (1.56%/pt-yr) is perfectly admissible, notwithstanding the fact that thromboembolism also occurs with bioprostheses. Nevertheless, it can be assumed that this percentage could be overestimated because all the episodes of CVA/TIA were classified as valve-related events and in most of them there was no echocardiographic information regarding the valve status, including the presence of thrombus. Furthermore, this specific population is also susceptible to central neurological events from other sources, such as aortic, carotid and vertebral artery disease.

We observed a lower rate of major bleeding events (0.84%/pt-yr), compared to others [13, 14], but higher than that reported in recent papers from Vicchio and colleagues [15] who had a 5- and 10-year freedom from bleeding of 98.7% and 98.3%, respectively. We believe that this low incidence of significant haemorrhage is partially due to patient selection (good compliance to anticoagulation therapy), to intensive nurse–patient education during hospitalization, explaining the necessity and risks of taking anticoagulants, and, perhaps, to an aggressive follow-up by the surgeons in the first months after discharge. In addition, levels of anticoagulation were kept marginally lower than those we use in younger patients. Naturally, this may have had an impact in the incidence of thromboembolism.

As expected, prosthetic endocarditis was a fearful event, with almost half of patients who experienced it dying as a consequence. Only three patients who had endocarditis are still alive and they were all treated conservatively.

Other reinterventions because of the aortic prosthesis were rare, consistent with other results in the literature, with 10- and 15-year freedom from reoperation of 96.9$\pm$2.4% and 96.4$\pm$2.6%, respectively, which is certainly lower than those usually described for bioprostheses after identical follow-up periods, even in this age group [4, 5].

There are several limitations of this study. Firstly, it is retrospective and the patients subject to selection bias, although the decision to use a mechanical valve was collegial and not by individual surgeons, which assured consistency. Because it represents a cross-sectional follow-up, data on valve-related complications were not collected on an ongoing basis. We tried to minimize this by a thorough search for adverse events and review of all the clinical files available looking for events that required hospitalization. Secondly, a comparison with a similar group of elderly patients undergoing bioprosthetic implantation would be of extreme value. But our selection criteria for mechanical valves precluded such comparison. Only a randomised study could solve this issue.

At the end of the study, about two-thirds of our patients were alive and free from MAVE. Hence, we consider implantation of a mechanical prosthesis in elderly patients safe and appropriate, but consider that the choice must be tailored for each specific patient.

References

[1] Vahanian A, Baumgartner H, Bax J, Butchart E, Dion R, Filippatos G, Flachskamp F, Hall R, Lung B, Kasprzak, Nataf P, Tornos P, Torracca L, Wenink A. ESC 2007 Guidelines on the management of valvular heart disease. The task force on the management of valvular heart disease of the European Society of Cardiology. Eur Heart J 2007;28:230–268.

[2] Bonow RO, Carabello BA, Chatterjee K, de Leon AC Jr, Faxon DP, Freed MD, Gaasch WH, Lytle BW, Nishimura RA, O'Gara PT, O'Rourke RA, Otto CM, Shah PM, Shanewise JS, Smith SC Jr, Jacobs AK, Adams CD, Anderson JL, Antman EM, Fuster V, Halperin JL, Hiratzka LF, Hunt SA, Lytle BW, Nishimura R, Page RL, Riegel B. ACC/AHA 2006 guidelines for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (writing Committee to Revise the 1998 guidelines for the management of patients with valvular heart disease) developed in collaboration with the Society of Cardiovascular Anesthesiologists endorsed by the Society for Cardiovascular Angiography and Interventions and the Society of Thoracic Surgeons. J Am Coll Cardiol 2006; 48:e1–e148.

[3] Oakley RE, Kleine P, Bach DS. Choice of prosthetic heart valve in today's practice. Circulation 2008;117:253–256.

[4] Cosgrove DM, Lytle BW, Taylor PC, Camacho MT, Stewart RW, McCarthy PM, Miller DP, Piedmonte MR, Loop FD. The Carpentier-Edwards pericardial aortic valve. Ten-year results. J Thorac Cardiovasc Surg 1995; 110:6516–6562.

[5] Frater RW, Furlong P, Cosgrove DM, Okies JE, Colburn LQ, Katz AS, Lowe NL, Ryba EA. Long-term durability and patient functional status of the Carpentier-Edwards perimount pericardial bioprostheses in the aortic position. J Heart Valve Disease 1998;7:48–53.

[6] Ruel M, Kulik A, Lam BK, Rubens FD, Hendry PJ, Masters RG, Bedard P, Mesana TG. Long-term outcomes of valve replacement with modern prostheses in young adults. Eur J Cardiothorac Surg 2005;27:425–433.

[7] Sidhu P, O'Kane H, Ali N, Gladstone DJ, Sarsam MA, Campalani G, MacGowan SW. Mechanical or bioprosthetic valves in the elderly: a 20-year comparison. Ann Thorac Surg 2001;71:S257–S260.

[8] Accola KD, Scott ML, Spector SD, Thompson PA, Palmer GJ, Sand ME, Suarez-Cavalier JE, Ebra G. Is the St. Jude Medical mechanical valve an appropriate choice for elderly patients? A long-term retrospective study measuring quality of life. J Heart Valve Dis 2006;15:57–66.

[9] Chan V, Jamieson WR, Germann E, Chan F, Miyagishima RT, Burr LH, Janusz MT, Ling H, Fradet GJ. Performance of bioprostheses and mechanical prostheses assessed by composites of valve-related complications to 15 years after aortic valve replacement. J Thorac Cardiovasc Surg 2006;131:1267–1273.

[10] Kurlansky PA, Williams DB, Traad EA, Carrillo RG, Schor JS, Zucker M, Ebra G. The valve of choice in elderly patients and its influence on quality of life: a long-term comparative study. J Heart Valve Dis 2006; 15:180–189.

[11] Butchart EG, Gohlke-Barwolf C, Antunes MJ, Tornos P, De Caterina R, Cormier B, Prendergast B, Lung B, Bjornstad H, Leport C, Hall RJ, Vahanian A. Working groups on valvular heart disease, thrombosis, cardiac rehabilitation, exercise physiology, European Society of Cardiology. Recommendations for the management of patients after heart valve surgery. Eur Heart J 2005;26:2463–2471.

[12] Akins CW, Miller DC, Turina MI, Kouchoukos NT, Blackstone EH, Grunkemeier GL, Takkenberg JJ, David TE, Butchart EG, Adams DH, Shahian DM, Hagl S, Mayer JE, Lytle BW. Guidelines for reporting mortality and morbidity after cardiac valve interventions. Eur J Cardiothorac Surg 2008;33:523–528.

[13] Florath I, Albert A, Rosendahl U, Alexander T, Ennker IC, Ennker J. Mid term outcome and quality of life after aortic valve rplacement in elderly people: mechanical versus stentless biological valves. Heart 2005;91:1023–1029.

[14] Masters RG, Semelhago LC, Pipe AL, Keon WJ. Are older patients with mechanical heart valves at increased risk? Ann Thorac Surg 1999; 68:2169–2172.

[15] Vicchio M, Corte AD, Feo MD, Santarpino G, Santo LS, Romano G, Caianiello G, Scardone M, Cotrufo M. Quality of life after implantation of bileaflet prostheses in elderly patients: an anticoagulation work group experience. Ann Thorac Surg 2007;84:459–465.

Conference discussion

Dr. P. Simon (*Al Kohober, Saudi Arabia*): You describe in your paper the outcomes of patients aged 65 years or older after aortic valve replacement with a mechanical prosthesis, and you conclude from your findings that this is a valid and safe practice. Your conclusion is well in line with several other recent publications, which could not demonstrate either a clear survival benefit, better freedom from adverse events, or quality of life advantages with bioprosthesis over mechanical prosthesis in the older age group. So is the pendulum swinging back after we have seen the indication for AVR using bioprosthesis being expanded to younger patients because of low rates of degeneration of the modern bioprosthesis, especially in older patients? So how do we resolve this dilemma and choose the right type of prosthesis for the individual patient? You stress in your manuscript very much the importance of careful patient selection, but you unfortunately do not tell us how you do this. So this leads me to a few questions.

How many patients received a bioprosthesis in the same age group during the same period and why is there no comparison? Secondly, what is the current practice of you and your institution and what are the actual selection criteria you used? Third, how do the current advances with transcatheter valve replacement technologies becoming available, and especially the concept of valve-in-a-valve replacement of a failing bioprosthesis, affect your current practice or will it do so in the near future?

Dr. Coutinho**:** Regarding the first question, as I mentioned in the manuscript, the policy of our department is to implant a mechanical prosthesis in a suitable patient. The suitable patient goes until 70–72-year-old patient. When we look at the results, two-thirds of the patients were alive at the end of the study, and the mean age of the patients alive was 82.1 years, which means that if we had implanted a bioprosthesis, probably this patient would be at risk of reoperation. The mean overall survival was 13.6 years, which I think is remarkable.

Regarding the selection, yes, the selection is by conversation with the patient, beginning with the nurse and the cardiologist and, afterwards, the surgeon; the performance status is analyzed; the capability of the patient to manage the anticoagulation; the family support of the patient to be anticoagulated. There are several factors that we take into account when deciding to implant a mechanical prosthesis, but we are not saying that older patients should have a mechanical prosthesis.

We decided to perform this study because this goes in the opposite direction of the recent tendency. The recent tendency is to use a bioprosthesis in increasingly younger patients. Well, with these results we can say that mechanical valve replacement is a safe and appropriate measure. There weren't exclusion or inclusion criteria to this study. This is a retrospective analysis.

Dr. Simon**:** So what is it you do now? Do you put mechanical valves in the patients 65 to 72, in all of them, or which ones?

Dr. Coutinho**:** No, no. I have just answered that, if the patient is suitable for a mechanical prosthesis.

Dr. J. Appoo (*Calgary, Alberta, Canada*): I have two questions. I think you had about 15% of patients at 10 years with a thromboembolic event but only three patients who had reoperation.

Dr. Coutinho**:** Five patients were reoperated.

Dr. Appoo**:** But none of them were reoperated for thromboembolism. So can you comment on that? If a patient has a thromboembolic event, do they usually require a reop or not? And secondly, at 10 years you had close to 30% of patients with a major thromboembolic or a bleeding event, which is actually a significant morbidity, and I don't think that can be underestimated.

Dr. Coutinho**:** About the second question, yes, the gross analysis of 18% of the patients having a thromboembolic event seems inadmissible, but the linearized incidence was 1.56 per patient year.

Dr. Appoo**:** But that is the whole point. 1.56 per patient year adds up to 15% at 10 years, which is actually quite a high incidence. One-third of patients had a major complication at 10 years.

Dr. Coutinho**:** One explanation for that is that we use a lower threshold for the level of anticoagulation. I don't know if that could be a reason for having a thromboembolic event. But the linearized incidence is around the values cited by other works in other population groups.