Is Routine Use of Stentless Aortic Prostheses Justified in an Elderly (aged ≥75 Years) Population?

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Background and aim of the study: **Stentless prostheses in the aortic position produce a superior hemodynamic profile in comparison to that with stented valves. To determine whether routine use of stentless valves in an elderly population is justified, a 10-year retrospective review was performed of a consecutive series of patients aged ≥75 years undergoing stentless aortic valve replacement (AVR).**

Methods: **Demographic, operative and mortality data were obtained retrospectively. Survivors were interviewed by telephone according to a defined protocol. Univariate and multivariate analysis was used to identify independent predictors of 30-day and overall medium-term mortality. Definitions and analyses were in accordance with joint STS/AATS guidelines.**

Results: **A total of 103 patients (57 males, 46 females; mean age 79.8 years; range: 75-91 years) underwent AVR with a either a Toronto stentless porcine valve (size range: 21-29 mm; n = 74) or an aortic homograft (n = 29). Twenty-eight patients (27%) had either urgent/emergency surgery, 12 (11%) underwent redo surgery, and in 54 cases (52%), the preoperative left ventricular function was significantly impaired (ejection fraction <50%). Forty patients (39%) also underwent concomitant coronary artery bypass grafting. The mean cross-clamp and cardiopulmonary bypass times were 105 ± 22 min and 144 ± 47 min, respectively. The overall 30-day mortality was 11.6% (n = 12). The 30-day mortality for all elective cases was 5.3%, but for isolated elective AVR was only 2.5%. Using a multivariate model, the only independent predictor of 30-day mortality and medium-term overall mortality was increasing age. The mean follow up period was 3.6 years (range: 0.1-9.3 years), and the Kaplan-Meier actuarial five-year survival was 52%. At follow up, 92% of patients were in NYHA functional classes I and II.**

Conclusion: **Stentless AVR in elderly patients is associated with excellent functional and survival outcome in the medium term. Furthermore, in elective cases, age alone should not be a deterrent to the routine use of stentless aortic valves.**

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Stentless prostheses, when implanted in the aortic position, produce a superior hemodynamic profile in comparison to that achieved with stented valves (1,2). Despite their recognized benefits, the use of stentless valves for aortic valve replacement (AVR) has not become common practice (3-6). Whilst the use of homografts is partially limited by their availability and involves specific processing and preservation, the stentless porcine valve does not suffer from these limitations. The implantation of stentless valves is technically more demanding, and this results in longer ischemic and cardiopulmonary bypass times (7). Consequently, many surgeons have continued to rely on the more conventional stented bioprostheses for replacement of the aortic valve in the elderly, and a full review addressing many of the issues was recently published (8).

Aortic valve surgery in the elderly is becoming more common, with increasing numbers of septuagenarians and octogenarians being referred for surgery. Aortic stenosis remains a unique pathological entity in the sense that surgery remains the only effective treatment modality. Evidence suggests that elderly patients have the potential to recover from and respond well to surgery, with improvements in quality of live and survival (9,10). The use of stentless valves in this age group may be particularly beneficial, as a greater proportion of patients have impaired left ventricular func-

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tion and/or are likely to require concomitant coronary artery bypass grafting (CABG) surgery, with both subgroups likely to benefit from a stentless valve (11). In order to determine whether the routine use of stentless valves in an elderly population is justified, a 10-year retrospective review was conducted among patients aged ≥75 years undergoing stentless AVR performed by one surgeon.

Clinical material and methods

Patients

A consecutive series of patients aged ≥75 years underwent AVR with a stentless aortic prosthesis. All patients received either an aortic homograft or a stentless porcine valve.

Bioprosthesis

The Toronto stentless porcine valve (St. Jude Medical, St. Paul, MN, USA) was the only stentless porcine valve utilized in this series.

Homograft

All homografts in this series were cryopreserved. The preparation of cryopreserved homografts has been reported by the present authors' group and others elsewhere (12). Homografts were procured under sterile conditions from brain-dead organ donors or cadavers within 24 h of death.

Surgical technique

A single surgeon (J.P.) performed all of the operations. With its scalloped outflow but circular inflow margins, the Toronto stentless porcine valve was implanted in the subcoronary position. Interrupted 4-0 Ethibond sutures were used to construct the inflow suture line, and a separate outflow suture line was constructed in a semi-continuous manner with 4-0 Prolene. The commissures were secured with horizontal mattress sutures of 3-0 Ethibond. No pledgets, felt or other foreign materials were used to suture the valve. In patients receiving a homograft, the aortic annulus was sized preoperatively using echocardiography, and an appropriately sized homograft was selected. Sixteen homografts were implanted using the freehand subcoronary technique. The homograft coronary sinuses were scalloped and the non-coronary sinus was preserved. In 13 patients the homograft was inserted as a free-standing root replacement with reimplantation of the coronary ostia. All operations were performed with standard extracorporeal circulation using a membrane oxygenator and vortex pump at 28°C. Myocardial protection was achieved using a combination of antegrade and retrograde cold blood cardioplegia.

Data acquisition

Demographic, operative and mortality data were obtained from prospectively collected information from the hospital cardiac surgical registry. Further data on individual events were obtained from direct patient interviews, hospital records, review of general practitioners' records, death certificates and autopsy reports. Serial echocardiographic reports were scrutinized for evidence of structural valve deterioration or non-structural valve dysfunction. Mortality was determined using the NHS strategic tracing system (NHS, UK), and survivors were contacted by telephone for interview to obtain performance status. Operational definitions were in accordance with joint guidelines issued by the Society of Thoracic Surgeons (STS) and the American Association for Thoracic Surgery (AATS) for reporting mortality and morbidity following cardiac valvular operations (13).

Echocardiographic details

Patients in the present series underwent annual echocardiographic follow up at the authors' institution. Two-dimensional images were obtained using standard apical five-chamber, parasternal short- and long-axis views. Continuous-wave Doppler was used to determine the presence and severity of any regurgitation.

Anticoagulation

None of the patients in this series was anticoagulated with warfarin. Aspirin was administered to those patients undergoing coronary artery surgery simultaneously, and also to those in atrial fibrillation, provided that there were no contraindications.

Statistical analysis

Data were expressed as mean ± SE. Actuarial Kaplan-Meier statistical methods were used to calculate the probability of survival and freedom from valve-related complications. Values that were not normally distributed were presented as median ± interquartile range (25-75%) (IQR_{25-75}). Variables were compared using Student's *t*-test, Mann-Whitney test, Fisher Exact test or chi-square test as appropriate, and a p-value <0.05 was considered to be statistically significant.

The survival of a patient started at the time of AVR and ended at the event of their death or at the time of the last follow up (censoring). Actuarial Kaplan-Meier statistical methods were used to calculate the probability of survival and freedom from valve-related complications. Preoperative variables were compared using univariate analysis with regard to the effect on 30-day mortality and all-cause, medium-term mortality. Those variables which proved to be significant (p <0.05) were

J Heart Valve Dis
Vol. 14. No. 1
January 2005

included in the logistic regression multivariate analysis (early mortality) or Cox proportional hazard regression model (medium-term mortality). All statistical analysis was performed using the SPSS 11.0 for Windows software package (SPSS Inc., Chicago, IL, USA).

Results

Between 1st January 1991 and 1st January 2001, a total of 455 aortic valve replacements was performed at the authors' institution using either a stentless porcine valve or a homograft. Among this cohort, 103 patients (22.9%) were aged ≥75 years (mean age 79.8 ± 3.1 years), of whom 57 (55%) were males. Seventy-four patients (72%) received a stentless porcine valve, while an aortic homograft was implanted in 29 cases (28%). In 13 (45%) of the patients who underwent homograft AVR the homograft was implanted as a free-standing full root, with re-implantation of the coronary 'buttons'.

Aortic stenosis was the indication for surgery in 73 cases (71%), 11 (11%) had aortic regurgitation, and 18 (17%) had mixed aortic valve disease. AVR was performed on an elective basis in 75 patients (73%), urgently in nine (9%), and as an emergency procedure in 19 (18%). Twelve (12%) of the cases were re-do AVR. Renal dysfunction, as indicated by an elevated serum creatinine level (>150 μmol/l) was identified in 20 (19%) patients on routine preoperative assessment. Left ventricular function, as assessed by cardiac catheterization or echocardiography, was noted to be impaired (ejection fraction <50%) in 55 patients (53%) prior to surgery. Concomitant coronary artery bypass grafting (CABG) surgery was performed in 40 patients (39%), with a mean of 1.6 grafts per patient. The mean cross-clamp and cardiopulmonary bypass (CPB) times were 105 ± 22 and 144 ± 47 min, respectively. Patient demographics and operative procedures are summarized in Table I.

The overall 30-day mortality was 11.6% (n = 12), but for all elective cases was 5.3% (n = 4). For patients undergoing isolated elective stentless AVR, the 30-day mortality was only 2.5%.

The mean medium-term follow up period was 3.6 years (range: 0.1 to 9.3 years). The one- and five-year actuarial survival was 82% and 52%, respectively (Fig.

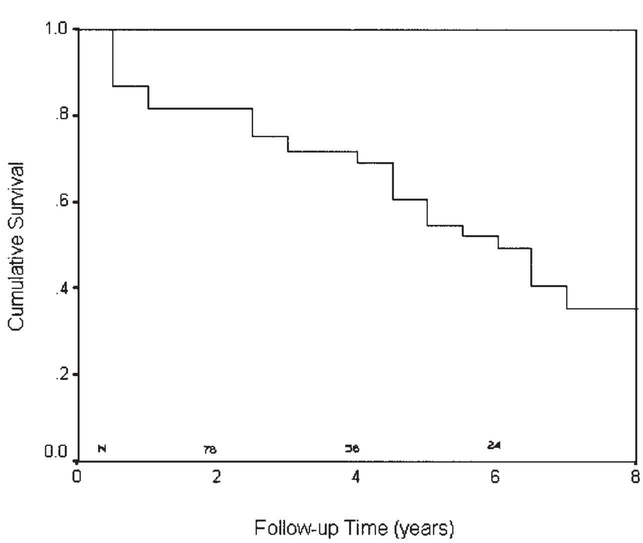

Figure 1: Actuarial overall survival including operative mortality.

Table I: Patient baseline and operative characteristics.

Parameter	No. of patients
Stentless valves	103
Stentless porcine valve	74
Subcoronary homograft	16
Homograft root replacement	13
Patient age (years)*	80 ± 4
Male gender	57 (55)
Diabetes	12 (11)
Hypertension	32 (31)
Serum creatinine (μmol/l)*	126 ± 90
Cross-clamp time (min)*	105 ± 22
CPB time (min)*	144 ± 47
Left ventricular function	
Good (EF >45%)	48 (47)
Moderate (EF 30-44%)	45 (44)
Poor (EF <30%)	10 (9)
Preoperative NYHA functional class	
I/II	41 (40)
III/IV	62 (60)
Operative urgency	
Elective	75 (73)
Urgent	9 (9)
Emergency	19 (18)
Re-do procedure	12 (11)
Operative indication	
Aortic stenosis	73 (71)
Aortic regurgitation	11 (11)
Mixed valve disease	18 (17)
Concomitant CABG	40 (39)
30-day mortality	12 (11)

*Values are mean ± SD.
Values in parentheses are percentages.
CABG: Coronary artery bypass grafting; CPB: Cardiopulmonary bypass; EF: Ejection fraction.

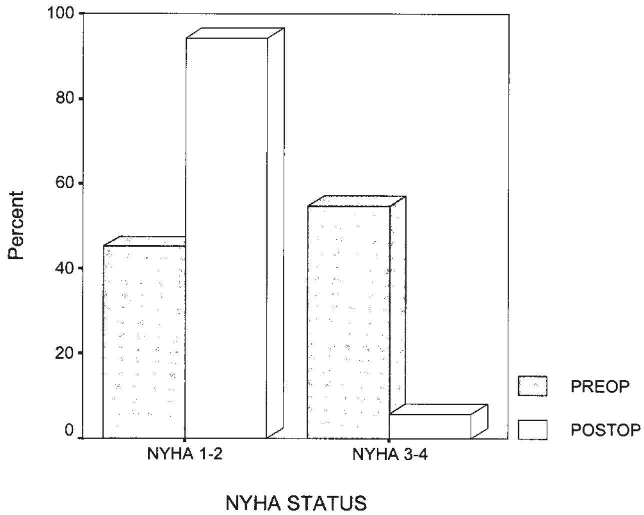

Figure 2: Preoperative and postoperative NYHA functional status.

1). Preoperatively, 60% of the patients were in NYHA functional classes III and IV, although at medium-term follow up only 8% had class III/IV symptoms (Fig. 2).

Univariate analysis was performed to identify risk factors for 30-day mortality (Table II). Increasing age ($p = 0.001$), emergency surgery ($p = 0.05$), redo operation ($p = 0.031$), root replacement ($p = 0.041$), increasing cross-clamp time ($p < 0.001$) and CPB time ($p < 0.001$) were significant predictors of 30-day mortality. Furthermore, patients who were not in sinus rhythm postoperatively and either in atrial fibrillation or

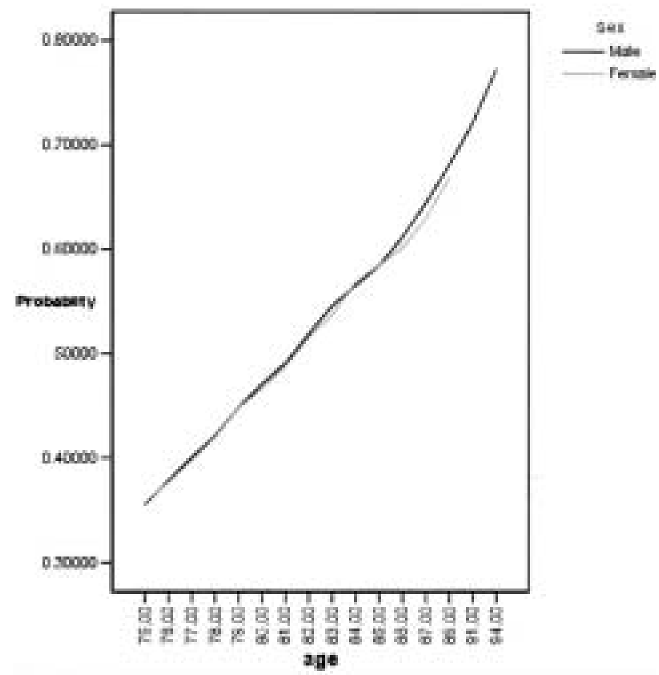

Figure 3: Probability of death in the medium term.

reliant on a pacemaker were identified as being at increased risk of early death in the univariate model ($p = 0.033$).

A second univariate analysis was undertaken to determine predictors of all-cause mortality in the medium term (Table II). The only significant variables identified as being independent predictors of death

Table II: Predictors of 30-day and medium term (mean follow up 3.6 years) mortality by univariate analysis.

Parameter	30-day mortality p-value	Medium-term mortality p-value
Increasing age	0.001	0.016
Increasing cross-clamp time	<0.001	-
Increasing CPB time	<0.001	-
Male gender	0.218	0.402
Revision surgery	0.031	0.784
Root replacement	0.041	0.990
Concomitant CABG	0.541	0.034
Left ventricular dysfunction (EF <50%)	0.128	0.575
Serum creatinine >150 μmol/l	0.691	0.239
Emergency surgery	0.05	0.408
Hypertension	1.00	0.982
Diabetes mellitus	1.00	0.221
Preoperative rhythm other than SR (paced or AF)	0.90	0.628
Rhythm at last follow up other than sinus (paced or AF)	0.033	0.433

AF: Atrial fibrillation; CABG: Coronary artery bypass grafting; CPB: Cardiopulmonary bypass; EF: Ejection fraction.

J Heart Valve Dis
Vol. 14. No. 1
January 2005

Table III: Predictors of 30-day mortality by multivariate analysis.

Parameter	Odds ratio (95% CI)	p-value
Increasing age	1.64 (1.20-2.22)	0.002
Revision surgery	4.98 (0.28-87.5)	0.272
Root replacement	2.21 (0.89-55.1)	0.629
Emergency surgery	5.21 (0.45-60.0)	0.185
Increasing cross-clamp time	1.01 (0.91-1.12)	0.825
Increasing CPB time	1.02 (0.95-1.10)	0.506
Rhythm at last follow up other than sinus (i.e. paced rhythm or AF)	1.20 (0.07-20.7)	0.897

AF: Atrial fibrillation; CPB: Cardiopulmonary bypass.

during the medium term of follow up was increasing age ($p = 0.016$) and concomitant CABG surgery ($p = 0.034$).

Multivariate analysis confirmed increasing age as the only independent predictor for both 30-day mortality (odds ratio 1.64, 95% CI 1.20-2.22; $p = 0.002$) and overall medium-term mortality with hazard ratio of 1.16 (95% CI 1.06-2.29; $p = 0.002$) (Tables III and IV).

The impact of increasing age at the time of surgery on the probability of overall survival in the medium term is shown in Figure 3. With increasing age at surgery, the negative impact on chances of survival in the medium-term follow up for the study was evident. There was no significant difference between the outlook for males and females.

Valve-related morbidity

One patient (0.9%) developed endocarditis at eight months postoperatively and was treated conservatively, with success. Freedom from endocarditis at both one and five years was 98.8%. Thromboembolic events were reported in six patients (6%), with five strokes and one transient ischemic attack. Of the five patients who suffered stroke, two were in atrial fibrillation, but neither was anticoagulated. Freedom from thromboembolism at one and five years was 97% and 89%, respectively.

Structural valve disease

Annual echocardiographic data were scrutinized to identify the development of structural valve disease. No patients in the present series developed progressive aortic regurgitation or hemodynamically significant aortic stenosis. This was reflected by the absence of any reoperations for valve failure.

Table IV: Predictors of overall medium-term mortality (mean follow up 3.6 years) by multivariate analysis.

Parameter	Hazard ratio (95% CI)	p-value
Increasing age	1.16 (1.06-2.29)	0.002
Concomitant CABG	1.21 (0.59-2.47)	0.609

CABG: coronary artery bypass grafting

Discussion

A number of investigators have now reported that stentless valves can be used safely in the elderly patient (14-16). The mean age of patients in the present analysis was 79.8 years, reflecting an older population than most other studies. In this series a significant number of patients had impaired left ventricular function, required concomitant coronary artery surgery, or underwent urgent/emergency surgery. Despite these factors, the 30-day mortality was 11%, reducing to 2.5% when only isolated elective AVR was considered. The low incidence of valve-related morbidity reported in several other published series evaluating stentless valves was also identified in the present series of patients aged ≥75 years although, as expected, thromboembolic events were more common among this age group, particularly in patients with atrial fibrillation.

Advocates of stentless AVR cite the more physiological performance of the prosthesis (17-19), which is largely attributable to preservation of the dynamic nature of the left ventricular outflow tract and aortic root. The avoidance of an obstructive stent results in lower postoperative transvalvular gradients at rest and during exercise (1,2), which is suggested to lead to a more rapid and complete regression of left ventricular hypertrophy (LVH) (11,20). Evidence from the long-term follow up of LVH in the Framingham study shows that LVH leads eventually to congestive cardiac failure and death. The eradication of diastolic dysfunction associated with severe hypertrophy in patients with aortic valve disease has been linked to a reduction in late death due to congestive heart failure (21). The concept of patient-prosthesis mismatch has led many to suggest that the use of stentless valves is the optimal manner by which to reduce disparity between prosthesis and patient size (1,19).

Despite the wealth of testimony towards the potential physiological and hemodynamic benefits of stentless prostheses, their use is not widespread. The heightened technical complexity of implanting a stentless valve, longer cross-clamp times and unfamiliarity with the procedure has led many surgeons to opt for a stented bioprosthesis or a mechanical prosthesis, primarily due to concerns that the above-mentioned factors may lead to a higher perioperative mortality. Although several investigators have quoted low early mortality following stentless AVR (22), the majority of these series have been reported from units wherein the operating surgeons have an interest and expertise in the routine use of stentless valves.

Concerns over a higher perioperative mortality due to the longer cross-clamp, CPB and procedure times may be unfounded. In the present series, the mean cross-clamp time was in excess of 100 min, while the mean CPB time exceeded 2 hours. In over one-quarter of patients, surgery was either urgent or emergent. Additionally, more than half of the patients undergoing stentless AVR in the present study had impaired left ventricular function. Despite these variables pointing to an increased operative risk, the early mortality was similar to that in other series reporting on a similar age group of patients with the co-morbid conditions as described. Most rewardingly, in the present study over 90% of survivors were in NYHA functional classes I or II at follow up. This may reflect the fact that elderly patients with ventricular dysfunction can also tolerate long ischemic times, provided that a stringent myocardial protection protocol is utilized in a manner similar to that in younger patients. It is likely that the most important factor in ensuring a good postoperative outcome after stentless AVR is a meticulous technique of valve implantation. This is highlighted in the present series by the absence of any early reoperations for aortic insufficiency, despite a predominant employment of the subcoronary technique for insertion. The only independent predictor of both early and late mortality was increasing age, though this merely reflected the life expectancy with increasing age and did not reflect valve function. Emergency surgery and redo procedures were found to be strongly significant risk factors for 30-day mortality, but were not found to be independent predictors on multivariate analysis. Accumulating evidence suggests that the routine use of stentless prostheses in elective aortic valve surgery is safe (14-16). However, in the very elderly patient in whom surgery is being performed on a non-elective basis, the most expeditious procedure possible, utilizing a conventional stented prosthesis, may yield the most satisfactory outcome.

In addition to the long-term benefits such as enhanced left ventricular mass regression, stentless prostheses also confer immediate advantages in terms of improved postoperative left ventricular function. Other reports have previously documented a greater reduction in left ventricular wall stress, superior systolic long axis function of the left ventricular free wall, and increases in fractional and circumferential shortening in comparison to stented valves (11). These functional improvements observed after stentless AVR may be important in preventing the development of postoperative low cardiac output states. The suggested superior hemodynamic properties of stentless valves have been based predominantly on the findings of observational studies (1,2,19,20). The most definitive means of assessing whether stentless valves confer important physiological and clinical advantages in comparison to stented prostheses is through prospective randomized evaluation. Two recently published trials comparing hemodynamic characteristics such as the extent of left ventricular mass regression did not reveal any significant difference between the two valve types (23,24). In this respect, further randomized studies are currently in progress, and additional data should be available in the near future.

Study limitations

The main study limitation was that most of the present patients, after a mean follow up of 3.6 years, were approaching 80 years of age. Clearly, data collected directly from patient interviews is likely to reflect inaccuracies due to poor memory and failure to recall. However, as the follow up data were acquired using a combination of the NHS Tracing system, general practitioners' records and reviews of hospital records, they should be complete. Nonetheless, it is recognized that the relatively low rates of thromboembolism reported herein likely reflects a failure to report minor episodes.

In conclusion, elderly patients recover well from cardiac surgery. As an increasing proportion of patients in this age group have an impaired left ventricular function, this subgroup may derive the most benefit from the more physiological stentless aortic prosthesis. The routine use of stentless aortic valves in elderly patients is associated with excellent functional and survival outcome in the medium term, without unduly increasing the operative risk. Furthermore, in elective cases, age alone should not be a deterrent in using stentless aortic valves routinely. Based on the present authors' experience with stentless AVR, it is felt that the routine use of aortic valves in the elderly is justifiable.

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Meeting discussion

DR. JOSE POMAR (Spain): Clearly, your group is used to implanting homografts on a routine basis. You say that the aortic cross-clamp time is about 105 minutes. Would you recommend the same policy for any surgeon?

DR. AYYAZ ALI (London, UK): Familiarity with the procedure is the major concern. If a stringent attitude is taken towards myocardial protection, then even despite the prolonged cross-clamp and bypass times, the procedure can be undertaken safely.

DR. POMAR: But the multivariate analysis showed age to be the most important issue, not valve matching.

DR. ALI: Exactly. It was not an independent predictor.

DR. MARC LASKAR (France): It was admirable to see the large number of homografts that you have implanted in elderly patients. Is that because in England you have a lot of homografts, for use in young and old people?

DR. ALI: Homograft availability at our center is good, and we have an established program. But if homograft limitation is an issue, the stentless porcine valve may be an alternative.

SIR MAGDI YACOUB (United Kingdom): What were the contraindications and exclusion criteria in this age group? Also, what is your opinion about calcification of the aortic wall around the coronary orifices in these patients as a contraindication for the use of an unstented valve - particularly if it is going to be a root?

DR. ALI: I am not aware that we had any contraindications, but if calcification of the aortic wall is a contraindication in terms of its geographical position for implantation of a stentless valve, then of course that would be taken into consideration. But we did not analyze the individual operative decision-making for each individual case.

MR. YACOUB: But that is really important. Is this is a one-surgeon experience?

DR. ALI: Yes, it is.

MR. YACOUB: How many prosthetic valves and/or stented valves were implanted in that age group by the same surgeon?

MR. J. PEPPER (United Kingdom): May I answer that? We did not have to remove a stentless valve because of calcification, but we avoided putting in a root in two patients because of calcification around the coronary ostia. During that period, about half of the patients in this age group also received stented valves.

MR. YACOUB: Prosthetic or stented?

MR. PEPPER: Sorry, I mean bioprosthetic.

MR. YACOUB: And what was the indication for that?

MR. PEPPER: It was almost all aortic stenosis.

MR. YACOUB: No, I mean for the use of a stented valve. A large root, for example?

MR. PEPPER: Yes, there may be a large root, or there may be patients who were particularly moribund, who were in cardiogenic shock.

DR. W. R. ERIC JAMIESON (Canada): If you had a hemodynamically favorable stentless valve or stented valve such as the new Carpentier Magna PERIMOUNT or the Mitroflow, would you consider putting it in a patient with a reduced life expectancy?

DR. ALI: We don't have long-term results, but we know that the stentless valve is more physiological in its design. I am sure that even elderly patients can gain some benefit from those more physiological characteristics. We have seen this in various hemodynamic data, that with preservation of the dynamic nature of the aortic annulus and the improvement of left ventricular function associated with stentless prostheses, elderly patients can benefit as much as younger patients. So if we can implant the stentless valve with a safe perioperative mortality and good circumstances, I don't see why we should not do that.

DR. JOSE POMAR (Spain): Would you reach the same conclusions if you had to use aortic roots instead of subcoronary stentless grafts?

DR. ALI: We only had a small number of aortic root replacements, so I can't comment on that. In this series the predominant insertion technique was subcoronary, and that was quite satisfactory.