

# Mid term outcome and quality of life after aortic valve replacement in elderly people: mechanical versus stentless biological valves

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**Objective:** To assess the benefit for patients older than 65 years of aortic valve replacement with stentless biological heart valves in comparison with mechanical valves.

**Design:** Multiple regression analysis of a retrospective follow up study.

**Setting:** Single cardiothoracic centre.

**Patients:** Between 1996 and 2001, 392 patients with a mean age of 74 years underwent aortic valve replacement with stentless Freestyle bioprostheses or mechanical St Jude Medical prostheses.

**Main outcome measure:** Operative mortality and morbidity, postoperative morbid events, mid term survival, and New York Heart Association (NYHA) class improvement, and quality of life.

**Results:** No significant differences were found between patients receiving stentless biological valves and patients receiving mechanical prostheses. However, analysis of subgroups showed that patients older than 75 years with mechanical valves had an increased risk of major bleeding events ( $p = 0.007$ ). Patients requiring anticoagulation by means of coumarin had a twofold increased risk of an impaired emotional reaction ( $p = 0.052$ ). However, for patients who received a mechanical valve for severe combined aortic valve disease a survival advantage ( $p = 0.045$ ) and a decreased risk of prolonged ventilation ( $p = 0.001$ ) was observed. On the other hand, patients receiving a stentless bioprosthesis had an increased risk of a prolonged stay in intensive care ( $p = 0.04$ ) and stroke ( $p = 0.01$ ) if they had severely reduced cardiac function (NYHA class IV).

**Conclusions:** Elderly people receiving stentless bioprostheses benefit emotionally because of the avoidance of coumarin. However, in patients with severe hypertrophied ventricles and extraordinary calcifications, stentless bioprostheses should be chosen with caution.

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Since the two large randomised trials of the 1970s comparing biological versus mechanical valves, patient characteristics, anticoagulation regimen, and the idea of tissue valve performance have changed because of technical progress and increasing life expectancy.<sup>1-3</sup> Most of the more recent studies comparing the long term results of bioprosthetic versus mechanical valves showed a significantly lower rate of complications caused by bioprosthetic valves,<sup>1,2,4-7</sup> whereas patients younger than 65 years had significantly higher reoperation rates.<sup>1,2,6,7</sup>

Since elderly patients especially benefit from bioprosthetic valves, because of the reduced incidence of structural failure in this age group, it is ethically questionable to conduct further randomised trials.<sup>8</sup> As a consequence of the altered implantation strategy, the characteristics of patients receiving biological valves differ from those receiving mechanical valves. This different distribution of risk factors concerning morbidity and mortality has to be considered. For this purpose multivariate regression analyses can be used.

Only Peterseim and colleagues<sup>7</sup> used multivariate regression analysis to study postoperative morbidity, whereas several other authors used this analysing method for survival<sup>4,6,9</sup> and some matched their groups by sex and age<sup>10</sup> and other potential risk factors.<sup>11</sup>

Avoidance of long term anticoagulation, and therefore the risk of bleeding or thromboembolic events, is intuitively associated with a higher quality of life. However, one of the few studies comparing quality of life after mechanical versus bioprosthetic valve replacement (AVR) found no difference in the group of middle aged patients.<sup>10</sup> Only patients undergoing AVR with pulmonary autografts were found to have a better

quality of life than that of patients receiving mechanical prostheses.<sup>12</sup>

Previous studies compared mechanical versus stented biological heart valves.<sup>1,2,5,6,7</sup> Haemodynamic advantages of stentless compared with stented bioprostheses anticipate a positive impact on quality of life and survival.<sup>13-16</sup>

In the present study, we performed a risk adjusted comparison of mechanical versus stentless biological prostheses in patients older than 65 years in terms of operative outcome, postoperative valve related morbidity, mid-term survival, and quality of life after AVR.

## PATIENTS AND METHODS

### Patient population

Between April 1996 and March 2001, 392 patients older than 65 years underwent AVR with either a stentless bioprosthesis (Medtronic Freestyle stentless bioprosthesis,  $n = 247$ ) or a mechanical prosthesis (St Jude Medical HP or standard,  $n = 145$ ). Bioprostheses were preferentially used in this age group. The prosthesis type and size were selected according to the surgeon's preference. One hundred and seventy seven patients (45%) underwent concomitant coronary artery bypass grafting (CABG). Patients undergoing other concomitant procedures were excluded from the analysis. Table 1

**Abbreviations:** AIC, Akaike information criterion; AVR, aortic valve replacement; CABG, coronary artery bypass grafting; CI, confidence interval; HR, hazard ratio; MP, mechanical prostheses; NHP, Nottingham health profile; NYHA, New York Heart Association; OR, odds ratio; QUADRA, quality assurance data review analysis; SB, stentless bioprostheses

**Table 1** Preoperative status

	Valve type		p Value*
	SB (n = 247)	MP (n = 145)	
Women	50%	34%	0.002
Age (years)	76 (5)	71 (4)	<0.001
BSA (m <sup>2</sup> )	1.82 (0.19)	1.89 (0.19)	0.002
BMI (kg/m <sup>2</sup> )	26 (4)	27 (4)	0.01
CABG	42%	50%	0.17
Previous CABG	1.6%	4.1%	0.18
Emergency operation	1.2%	4.1%	0.08
Previous MI	12%	22%	0.009
Diabetes mellitus	20%	24%	0.37
Hypertension	68%	70%	0.67
Hyperlipidaemia	44%	44%	1
History of renal disease	11%	13%	0.6
NYHA class			0.07
I	7%	4%	
II	33%	28%	
III	52%	52%	
IV	8%	16%	

Values are percentages or mean (SEM).

\* $\chi^2$  test or Mann-Whitney test.

BMI, body mass index; BSA, body surface area; CABG, coronary artery bypass grafting; MP, mechanical prosthesis; MI, myocardial infarction; NYHA, New York Heart Association; SB, Medtronic Freestyle stentless bioprosthesis.

shows the operative and preoperative characteristics of the patient population for each valve type. Patients receiving a stentless bioprosthesis were older and more were women. Figure 1 shows the distribution of valve size for male and female patients receiving various sizes of valves.

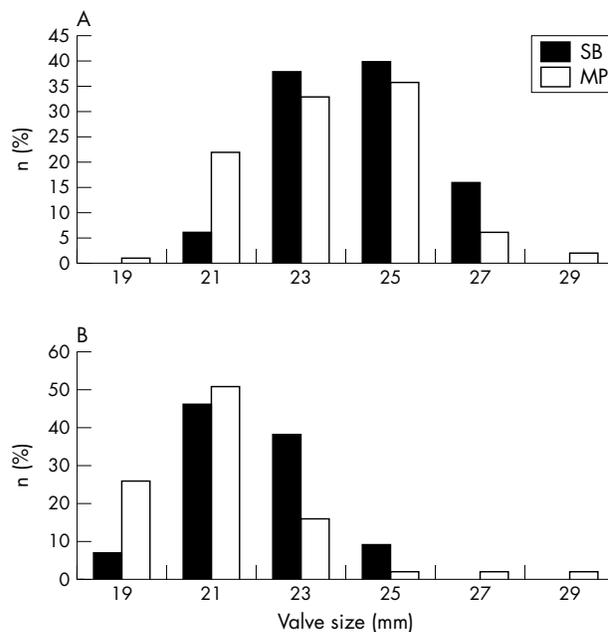
### Follow up

Follow up information was obtained in July 2001 by mailed questionnaires and was completed by telephone interviews. Follow up varied between three and 66 months. The questionnaire consisted of the Nottingham health profile (NHP), assessing quality of life, and general questions concerning postoperative complications, further stay in hospital care, New York Heart Association (NYHA) status, etc.<sup>17</sup> Answers indicating serious events such as bleeding, reoperation, and endocarditis were verified by telephone contact. The NHP contains 38 subjective statements divided into six sections: energy, pain, emotional reaction, sleep, social isolation, and physical mobility. The number of statements in each section varies from three in the energy section to nine in the emotional reaction section. Scale scores range from 0 to 100, with a lower score indicating a better perceived quality of life.

### Statistical analysis

Data were analysed with the software package SPSS (SPSS Inc, Chicago, Illinois, USA). All continuous data were expressed as mean (SEM) and compared by the Mann-Whitney test. Dichotomic variables were evaluated by the univariable  $\chi^2$  test and Fisher's exact test.

As the preoperative characteristics of patients receiving stentless bioprostheses and mechanical prostheses differed, potential confounders have to be considered by multivariate regression analyses. Overall survival after AVR was analysed by Cox regression. The following categorical outcome variables were analysed by logistic regression: operative mortality (death within 30 days after operation), stay in intensive or intermediate care longer than five days, and prolonged ventilation (> 1 day). As we were interested in the difference in the number of events (rate) and not in the time to the event for the categorical follow up outcome variables such as valve related morbidity, quality of life, and NYHA status, we also used logistic regression. To control for the variable follow



**Figure 1** Valve size distribution for (A) male and (B) female patients undergoing aortic valve replacement (AVR) with Medtronic Freestyle stentless bioprosthesis (SB) and mechanical St Jude Medical prosthesis (MP).

up durations, follow up duration was regarded as a potential confounder in every logistic regression model.

As the scores for each section of the NHP were not normally distributed (more than 50% of patients scored 0—that is, the median is 0), we converted the scores into a binary variable. A score below the 75% quartile was coded as 0 and a score above or equal to this value was coded as 1, which corresponds to an impaired quality of life in the respective NHP section. Deterioration of the NYHA class after the operation was also coded as a binary variable: 0 was assigned to patients who were in the same or a lower NYHA class and 1 was assigned to patients who were in a higher NYHA class.

To compare valve related complications with those in previous studies, we calculated the crude linearised rate of events (number of events divided by the duration of follow up in years for all patients).

Data were collected on all patients as a part of QUADRA (quality assurance data review analysis), a national quality assessment trial of cardiothoracic surgery with standardised protocols of the German Society of Thoracic and Cardiovascular Surgery.<sup>18</sup> The following variables were regarded as potential confounders: age, sex, body mass index (kg/m<sup>2</sup>), body surface area (m<sup>2</sup>), body length (cm), body weight (kg), concomitant CABG, emergency procedure, re-replacement of the aortic valve, NYHA class, physiological subgroup with aortic stenosis, aortic insufficiency, or combined aortic valve disease (aortic stenosis and insufficiency, both grade II or more), history of congestive heart failure, previous myocardial infarction (< 90 days), history of syncope, history of venous or arterial embolism, hyperlipidaemia (treated), hypertension (treated), diabetes mellitus (treated by diet or medication), previous CABG, atrial fibrillation, heart pacemaker, peripheral occlusive arterial disease (intermittent claudication or previous vascular surgery), internal carotid artery stenosis (> 70%), neurological disorders (affecting ambulation or day to day functioning), history of renal disease, chronic pulmonary disease, and follow up duration.

For variable selection of all multivariate regression models, the Akaike information criterion (AIC = deviance of the model + 2 × number of included parameters) was calculated for variables differing from the outcome variable with  $p \leq 0.25$ . Variables of the model that had the smallest AIC were taken into new models. AIC values of all models containing one of the interesting variables and the new variable were recalculated. Variables of the model that had the smallest AIC were taken into new models containing one of the interesting variables and the two new selected variables. New variables were included until no further decrease in AIC was observed. To improve the predictive power of a model, combinations of risk factors were included if the AIC could be further decreased.

To establish linear dependence of outcome from continuous variables, the patient population was divided into four subgroups (quartiles) of the same size. The percentage of the analysed event was calculated for each subgroup. In the case of a non-linear increase or decrease of an event, the AIC was determined for variables that had a higher incidence of the outcome in one subgroup than in the others.

As the two compared patient groups (stentless bioprostheses and mechanical prostheses) differed in preoperative characteristics, interactions between the variables and the valve type with the smallest AIC were also included in the model. These interactions show the impact of the type of implanted valve in the patient subgroups. With the final model being established, the two patient groups were compared and the *p* value of model improvement was calculated by the likelihood ratio test.

## RESULTS

### Perioperative mortality and morbidity

#### Operative mortality

Fifteen patients (3.8%) died within 30 days after AVR. Preoperative risk factors for operative mortality were previous myocardial infarction (odds ratio (OR) 7.6, 95% confidence interval (CI) 2.38 to 24.56), hypertension (OR 7.6, 95% CI 0.94 to 61.42), and body mass index greater than 29 for female patients (OR 6.6, 95% CI 1.90 to 23.12). The *c* index of the model was 0.77. There was no difference in operative mortality between recipients of mechanical and of stentless biological prostheses ( $p = 0.92$ ).

To compare the operative morbidity of the two groups, stay in intensive care and length of ventilation were analysed.

#### Stay in intensive care unit

Mean stay in intensive care (including intermediate care) was 6 (14) days; 28% of patients stayed in the intensive care unit longer than five days. Risk factors for a prolonged stay in intensive care (> 5 days) were age (OR 1.11, 95% CI 1.06 to 1.16), history of renal disease (OR 2.4, 95% CI 1.21 to 4.62), previous myocardial infarction (OR 1.98, 95% CI 1.06 to 3.68), hypertension, and advanced NYHA class (OR 1.89, 95% CI 1.17 to 3.06). Patients with hyperlipidaemia had the advantage of a shorter stay in the intensive care unit (OR 0.5, 95% CI 0.3 to 0.83). The *c* index was 0.7. There was no overall difference between the stentless bioprosthesis and mechanical prosthesis groups ( $p = 0.35$ ) but patients who were in NYHA class IV before the operation had an increased risk of a prolonged stay in intensive care if they received a stentless bioprosthesis (OR 3.3, 95% CI 1.13 to 8.95).

#### Duration of mechanical ventilation

Mean duration of ventilation was 2 (7) days; 19% of patients had prolonged ventilation (> 1 day). Predictors for prolonged ventilation were age (OR 1.07, 95% CI 1.02 to 1.13), concomitant CABG (OR 2.3, 95% CI 1.31 to 4.04), previous CABG (OR 7.7, 95% CI 1.95 to 30.15), and emergency

procedure (OR 5.2, 95% CI 1.27 to 20.91). Patients with hyperlipidaemia had the advantage of a shorter duration of ventilation (OR 0.5, 95% CI 0.28 to 0.91). The *c* index of the model was 0.71. Including the interaction term, mechanical valve, and combined aortic valve disease (OR 0.21, 95% CI 0.07 to 0.62) improved the model significantly ( $p = 0.001$ ) and the *c* index increased to 0.74. For all patients receiving mechanical valves no significant difference in the risk of prolonged ventilation was found ( $p = 0.12$ ).

### Mid term survival

Follow up was 99% (390) complete with 69 deaths, including operative mortality, over 977 patient years. Mean follow up duration was 30 (18) months, which did not differ for the two groups ( $p = 0.9$ ).

### Time related survival

There was no significant difference in mid term survival after AVR between the two valve type groups ( $p = 0.56$ ). Diabetes mellitus (hazard ratio (HR) 2.1, 95% CI 1.26 to 3.55), advanced NYHA class (HR 2.1, 95% CI 1.13 to 4.05), previous myocardial infarction (HR 1.9, 95% CI 1.11 to 3.23), history of renal disease (HR 2.3, 95% CI 1.23 to 4.14), atrial fibrillation (HR 1.9, 95% CI 1.06 to 3.3), higher age (HR 1.06, 95% CI 1.02 to 1.12), and male sex (HR 1.8, 95% CI 1.02 to 3.14) were significantly associated with survival duration. Patients with combined aortic valve disease had a significant ( $p = 0.02$ ) survival advantage if they received a mechanical valve (HR 0.38, 95% CI 0.15 to 0.96).

### Response to questionnaires

There was an 86% response rate to the questionnaires (279 of 323 survivors). As 44 patients did not respond, we analysed whether there was a difference between the mechanical prosthesis and stentless bioprosthesis groups. Risk factors for not answering the questionnaire were increasing body mass index (OR 1.09, 95% CI 1.001 to 1.19), increasing follow up duration for female patients (OR 1.02, 95% CI 1.00 to 1.03), chronic pulmonary disease and history of renal disease (OR 8.0, 95% CI 2.2 to 29.1), and prolonged mechanical ventilation (> 1 day) after AVR (OR 3.6, 95% CI 1.6 to 7.9). The *c* index of the model was 0.71. The difference between the stentless bioprosthesis and mechanical prosthesis groups in general was not significant ( $p = 0.93$ ).

### Valve related morbidity

Table 2 shows the risk factors for valve related morbidity such as prosthetic valve endocarditis, reoperation, bleeding events, and stroke.

### Prosthetic valve endocarditis

The linearised rate of prosthetic valve endocarditis was 0.6% and 0.3% per patient year in the stentless bioprosthesis and mechanical prosthesis groups, respectively. There was no significant difference between the two groups ( $p = 0.96$ ) with a very good predictive power for the model (table 2; *c* index = 0.89).

### Reoperation

The rate of reoperation was 0.9% and 0.3% per patient year for the stentless biological and mechanical valve groups, respectively, with no significant difference for all patients ( $p = 0.42$ ). Patients with aortic stenosis receiving stentless bioprostheses had a significant ( $p = 0.04$ ) increased risk of reoperation (table 2). The *c* index was 0.96.

### Major bleeding events

Major bleeding events were observed with an incidence of 1.1% and 2.2% per patient year for biological and mechanical

**Table 2** Regression models for valve related morbidity

Risk factors	p Value*	OR	95% CI
Prosthetic valve endocarditis			
Follow up duration (months)	0.048	0.84	0.7 to 0.99
Reoperation			
BMI >29 kg/m <sup>2</sup>	0.05	8.0	1.0 to 63.4
Surgical complications	<0.001	64	6.4 to 644.4
AS + stentless biological valve	0.08	11.6	0.8 to 177.3
Bleeding events			
Neurological disorders	0.001	21.5	3.5 to 132.5
Peripheral occlusive arterial disease	0.028	9.7	1.3 to 73.7
Mechanical valve + age >75 years	0.007	18.9	2.2 to 163.0
Stroke			
Atrial fibrillation at discharge	0.012	4.1	1.4 to 12.5
Female + AS	0.033	3.2	1.1 to 9.5
Female + internal carotid artery stenosis	0.001	12.1	2.7 to 53.6
Stentless biological valve + NYHA IV	0.007	9.5	1.9 to 48.4

\*Wald test for variables included in the model.

AS, aortic stenosis; CI, confidence interval; OR, odds ratio.

prostheses, respectively. All patients receiving a mechanical valve required anticoagulation, whereas in the stentless bioprosthesis group 21% required this treatment for concomitant diseases. Patients older than 75 years receiving mechanical valves had a nearly 19 times increased risk of bleeding events (table 2), whereas the risk of all patients receiving mechanical valves was not significantly increased ( $p = 0.09$ ). The c index of the model was improved from 0.75 to 0.81 by including the interaction term mechanical valve and age over 75 years.

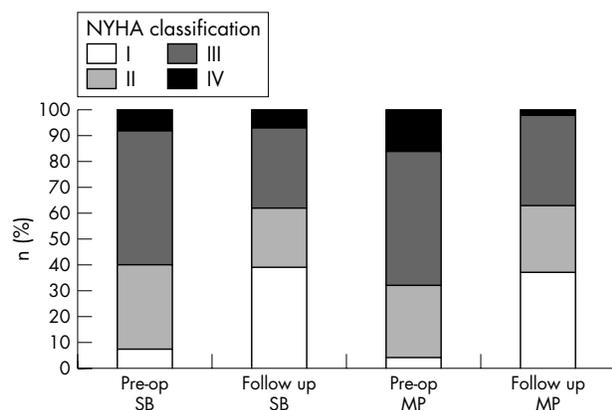
### Stroke

The linearized rate of stroke was 3.2% and 1% per patient year for stentless the bioprosthesis and the mechanical prosthesis groups, respectively. The difference between the two groups was still not significant ( $p = 0.1$ ). After analysis of all interactions of valve types and characteristics, which had a different proportion in the two groups, patients receiving biological stentless valves had an increased risk if they were in NYHA class IV before AVR (OR 9.5, 95% CI 1.9 to 48.4). After inclusion of this term in the model, the model improved significantly ( $p = 0.01$ ) and the difference between the two groups became less significant ( $p = 0.22$ ). The model (table 2) had a c index of 0.8.

### NYHA class and quality of life

#### NYHA class

In fig 2, the distribution of NYHA class is shown before and after AVR for stentless biological and mechanical valves. In



**Figure 2** Distribution of New York Heart Association (NYHA) class before (preOP) and after AVR with SB and MP.

general, the NYHA status improved after AVR. In 14% of the patients NYHA status deteriorated during follow up. Preoperative risk factors of deterioration of the NYHA status from before to after AVR were age (OR 1.1, 95% CI 1.03 to 1.19) and history of syncope (OR 3.9, 95% CI 1.53 to 9.94). NYHA status deterioration depended on follow up duration ( $p = 0.002$ ), in that patients questioned a longer time after AVR had a lower risk of having deterioration (OR 0.96, 95% CI 0.94 to 0.99). The predictive power of the model was 0.74. There was no significant difference between the two groups ( $p = 0.28$ ).

### Quality of life

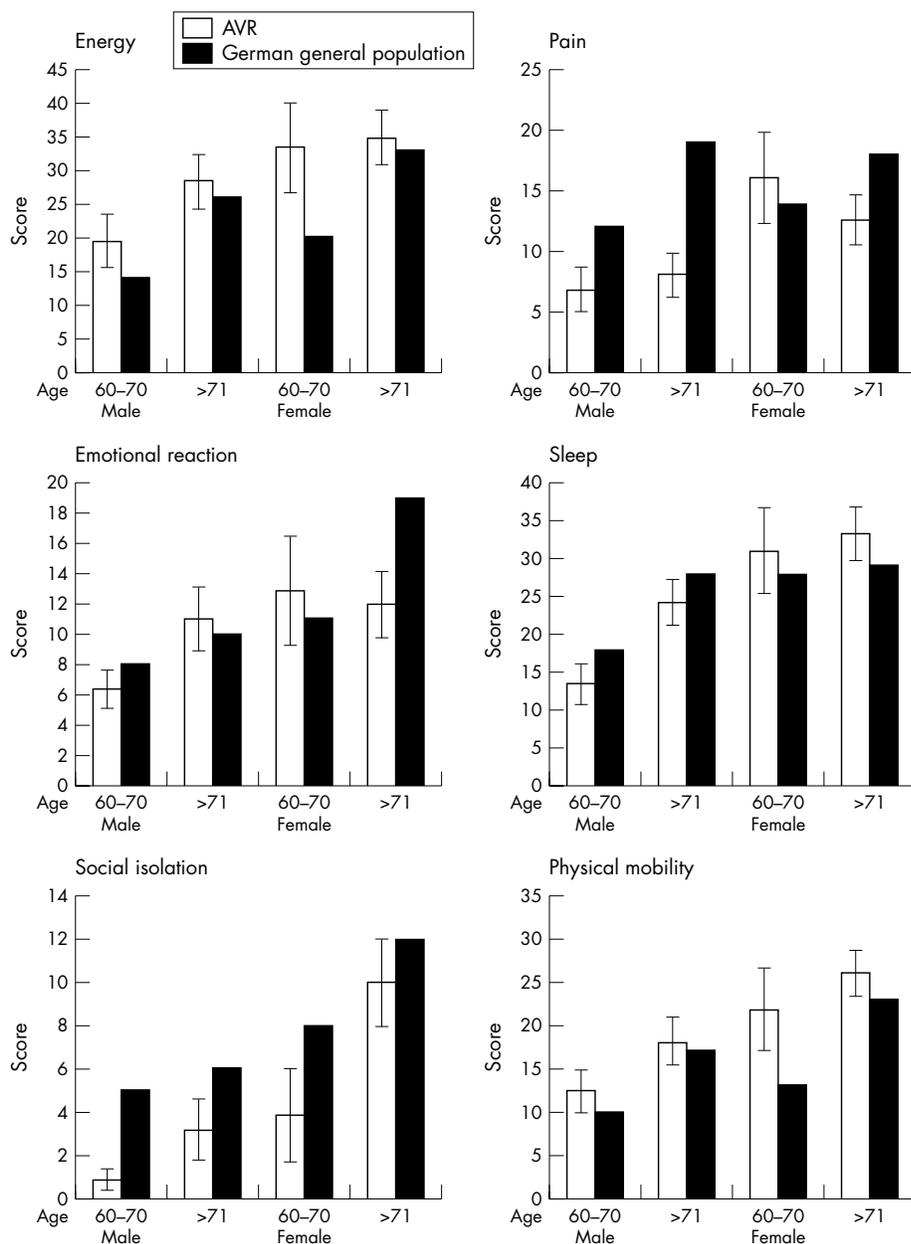
The results of the NHP questionnaire were compared with results of the German general population.<sup>19</sup> In general, the scores were comparable (fig 3). Patients after AVR had a lower score in the social isolation section. Subgroup analyses showed that patients between 60–70 years old had higher scores in the energy section; female patients in this age group had a higher score for physical mobility. The score for pain was lower for male patients after AVR in than among the general population.

The incidence of a score higher than the 75th quartile was 11% per patient year for energy, 8% for pain and emotional reaction, 9% for sleep, 6% for social isolation, and 10% for physical mobility. Table 3 presents the risk factors for an impaired score for each section. The c indices for the models were 0.7 for energy, 0.7 for pain, 0.72 for emotional reaction, 0.69 for sleep, 0.82 for social isolation, and 0.69 for physical mobility.

Patients requiring anticoagulation had nearly a twofold increased risk for an impaired emotional reaction (OR 1.9, 95% CI 0.98 to 3.68). No significant differences were found between recipients of stentless biological and of mechanical valves and between patients requiring anticoagulation and patients not requiring anticoagulation in all other sections: energy ( $p = 0.6$ ,  $p = 0.87$ ), pain ( $p = 0.2$ ,  $p = 0.26$ ), sleep ( $p = 0.54$ ,  $p = 0.14$ ), social isolation ( $p = 0.73$ ,  $p = 0.91$ ), and physical mobility ( $p = 0.58$ ,  $p = 0.22$ , respectively).

### DISCUSSION

Patients receiving biological stentless or mechanical prostheses had similar overall outcomes in this study. Patients undergoing AVR with stentless bioprostheses did not have an increased operative risk.<sup>20</sup> A survey of the literature concerning long term survival found a survival advantage for patients with mechanical prostheses in comparison with bioprostheses in large randomised studies.<sup>1,2</sup> Studies considering



**Figure 3** Mean scores and 95% confidence intervals in each section of the Nottingham health profile of patients after AVR with SB and MP in comparison with the German general population by sex and age group.

confounders by matching their groups by age and sex<sup>10 11 21</sup> and by risk adjusted analyses with Cox regression did not detect any survival differences.<sup>6 7 9</sup> This may be related to some extent to the earlier study time of the randomised studies, when bioprostheses were less developed.

Previous Cox regression analyses identified simultaneous CABG,<sup>7 9</sup> coexisting coronary artery disease,<sup>22</sup> reoperation,<sup>9</sup> age, NYHA class IV, diabetes mellitus,<sup>6 7</sup> renal disease, lung disease, ejection fraction less than 40%,<sup>7</sup> and atrial fibrillation<sup>23</sup> as predictors of survival. In addition to previously found risk factors male sex was identified as an independent predictor of survival after AVR. This may be explained by differences in the study design: our study population was on average 10 years older. Therefore, male sex was identified as an independent risk factor reflecting the lower life expectancy for men in the general population.

An impact of the valve type on patient outcome was detected only if subgroups were analysed. Firstly, we confirmed an increased risk of major bleeding events if

coumarin was given to very old patients. The linearised rates of bleeding events detected in our study were comparable with the rates reported in the literature, which varied between 0.3–2.2% per patient year for bioprostheses and between 1.2–3.9% per patient year for mechanical prostheses.<sup>1 2 7 11</sup> Our analysis of quality of life showed that patients requiring anticoagulation had an impaired emotional reaction. This corresponds to the findings of Myken and colleagues<sup>21</sup> that over 40% of patients receiving mechanical valves described a negative impact of the anticoagulation on their quality of life and that over 70% of patients receiving bioprostheses felt that the absence of anticoagulation had a positive impact on their quality of life. However, by using standardised quality of life questionnaires, we and others observed a positive effect of AVR on the physical and most of the mental health categories in the elderly.<sup>24–26</sup> We observed a similar quality of life after AVR to that of the average man and woman of the same age (fig 3). Perchinsky and colleagues<sup>10</sup> found no difference in the quality of life between

**Table 3** Regression models for impaired quality of life

Risk factors	p Value*	OR	95% CI
<b>Energy</b>			
Age >78 years	0.057	1.9	0.98 to 3.6
Female	0.052	1.8	0.99 to 3.1
Advanced NYHA class	0.002	2.6	1.4 to 4.8
History of venous or arterial embolism	0.006	8.2	1.8 to 36.5
History of congestive heart failure + AS	0.046	2.4	1.0 to 5.6
<b>Pain</b>			
Female	0.026	2.0	1.1 to 3.9
Advanced NYHA class	0.027	2.2	1.1 to 4.3
Hypertension	0.064	2.1	0.96 to 4.47
History of renal disease	0.006	3	1.4 to 8.9
History of venous or arterial embolism	0.053	4.2	0.98 to 18.1
<b>Emotional reaction</b>			
Previous CABG	0.042	3.6	1.06 to 26.96
Neurological disorders + female sex	0.007	5.6	1.62 to 20.04
Chronic pulmonary disease + combined AVD	0.053	2.19	0.99 to 4.83
BMI <22 kg/m <sup>2</sup>	<0.001	5.35	2.2 to 12.97
Coumarin	0.058	1.9	0.98 to 3.68
<b>Sleep</b>			
Female	0.003	2.5	1.4 to 4.5
Age >73 years	0.014	2.2	1.2 to 4.0
Advanced NYHA class	0.033	2.0	1.1 to 3.7
Atrial fibrillation + non-elective procedure	0.018	6.2	1.4 to 27.9
<b>Social isolation</b>			
Age	0.018	1.09	1.02 to 1.18
BMI	0.003	0.85	0.76 to 0.94
Pulmonary disease	0.012	2.6	1.2 to 5.7
Female	0.001	3.9	1.7 to 8.8
AS	0.031	2.4	1.1 to 5.2
<b>Physical mobility</b>			
Female	0.024	2.0	1.1 to 3.6
Age	0.026	1.07	1.01 to 1.13
NYHA class IV	<0.001	6.8	2.5 to 19.0
Syncope and pulmonary disease	0.049	3.3	1.0 to 11.1

\*Wald test for variables included into the model.  
AS, aortic stenosis; AVD, aortic valve disease.

sex and age matched groups of patients receiving mechanical or biological valves with the short form-12 survey. Another matched study found that patients receiving mechanical heart valves had a higher degree of anxiety for reoperation and thromboembolic events.<sup>21</sup>

The positive effect of biological valves on a decreased bleeding rate and a better emotional reaction, when coumarin becomes unnecessary, may still be more pronounced with the stentless biological valve, since coumarin can be totally left out, in comparison with the stented biological valve, with which anticoagulation is recommended for 6–12 weeks postoperatively.

However, in this study this valve type also had negative effects in some patient subgroups.

Patients who were in NYHA class IV before AVR and who received stentless bioprostheses had an increased risk of stroke and prolonged stay in the intensive care unit. This probably reflects the demanding implantation technique of stentless valves, which leads, among other things, to longer clamping and bypass times. In patients in NYHA class IV, these consequences can be considered unfavourable.

The linearised rate of stroke was relatively high (3.2% per patient year), which may be explained by the advanced age of the patient population (mean age 74 years) and the inclusion of strokes appearing directly after operation into the analysis.

Patients with aortic stenosis may have a higher risk of reoperation if they received a stentless biological valve. Three patients with extreme hypertrophy of the left ventricular outflow tract underwent reoperation two days to three months after the primary AVR because of very high subvalvar and valvar gradients. Others have also reported high postoperative transvalvar gradients in stentless aortic valves, caused mainly by intramural haematomas and distortion of

the inflow cloth.<sup>27–28</sup> According to Westaby and colleagues,<sup>27</sup> this can be avoided by optimisation of intraoperative sizing and orientation of the valve and diminishes with time through expansion and remodelling of the porcine root, resolution of the paravalvar haematoma, and normalising of the acute inflammatory response. To avoid the risk of a high postoperative gradient with stentless valves, other authors suggest using the total aortic root technique instead of the subcoronary technique.<sup>29–30</sup> However, this technique increased mortality in older patients.<sup>31</sup> The other reoperations in the mechanical valve and bioprosthesis groups were for prosthetic valve endocarditis. No structural valve deterioration was observed within five years after implantation in either group. Linearised rates of prosthetic valve endocarditis and reoperation for our mechanical and stentless biological valve recipients were consistent with the findings of other studies.<sup>1–4–7–11–21</sup>

Patients with combined aortic valve disease had a lower risk of prolonged ventilation and a better chance of survival when receiving mechanical valves. Patients with combined aortic stenosis and regurgitation generally have a particularly unfavourable prognosis because there is both volume and pressure overload on the left ventricle.<sup>22</sup> The morphology of valves with combined stenosis and regurgitation resembles an aortic stenosis, but often the disease is more advanced and the pathology more complex.<sup>22–32</sup> In case of distortion of the annulus or more calcifications of the texture of the native valve, especially of the sinus, suturing of the stentless valve in the subcoronary technique is more demanding and may bear a high risk of complications in these patients.<sup>28</sup> While some authors suggest managing that risk by optimising operative techniques<sup>27</sup> (such as thorough decalcification), others suggest full root replacement<sup>29–30</sup> or even using other valve types.<sup>28</sup>

Interestingly, patients with a preoperative diagnosis of hyperlipidaemia had a shorter length of ventilation and shorter stay in the intensive care unit. Whether their better nutritional status gives patients with hyperlipidaemia an advantage in the intensive care unit or this phenomenon reflects more advanced cardiac disease in patients without hyperlipidaemia is unclear and should be studied further.

In general, patients benefit emotionally from avoidance of anticoagulation. In particular, very old patients profit from a lower risk of bleeding. However, the indication for a stentless biological valve should consider the demanding operative technique, especially in patients with more complex aortic valve pathologies.

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