

# Tissue Versus Mechanical Prostheses: Quality of Life in Octogenarians

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**Background.** The aim of this study was to determine whether changes in prognosis and quality of life (QOL) after aortic valve replacement (AVR) in octogenarians differ depending on the choice of mechanical (MP) or tissue (BP) valves.

**Methods.** Between July 1992 and September 2006, 160 consecutive octogenarians underwent AVR with (18.8%) or without concomitant coronary artery bypass grafting. At follow-up (mean  $3.4 \pm 2.8$  years, 552 patient-years, 98.3% complete), 121 were still alive and answered the Medical Outcomes Study Short-Form 36 Health Survey (SF-36) QOL questionnaire.

**Results.** Group BP had 62 patients. Group MP had 98 patients. Preoperative risk factors were comparable except group BP was older. Global hospital mortality was 8.8%. There were 21 late deaths, 61.9% of which were not valve- or anticoagulation-related. A significant difference emerged in 1-, 3-, 5- and 8-year actuarial survival rates (BP:  $86.4\% \pm$

$0.04\%$ ,  $76.9\% \pm 0.06\%$ ,  $58.1\% \pm 0.1\%$ ,  $46.5\% \pm 0.14\%$ , respectively, vs MP:  $91.3\% \pm 0.03\%$ ,  $88.6\% \pm 0.03\%$ ,  $81.6\% \pm 0.05\%$ ,  $70\% \pm 0.67\%$ ;  $p = 0.025$ ) but not in terms of 8-year freedom from valve-related complications ( $82.6\% \pm 0.1\%$  vs  $87\% \pm 0.053\%$ ,  $p = 0.55$ ). One anticoagulant-related hemorrhage occurred in group MP; one stroke occurred in group BP. Survivors had significant improvement in New York Heart Association functional class compared with preoperatively ( $1.1$  vs  $2.8$ ,  $p < 0.001$ ) Mean QOL scores were satisfactory and substantially comparable between the two groups; in seven domains, scores were higher than those of the age- and sex-matched general Italian population.

**Conclusions.** Long-term survival after AVR in selected octogenarians was similar to that of the general elderly population. The device type exerted no influence on QOL.

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The increase in life expectancy in Western populations, as well as improvements in surgical standards and postoperative care, has resulted in an increase in the proportion of people aged older than 80 years referring to cardiac surgical procedures. In the last 15 years, many authors have demonstrated that aortic valve replacement (AVR) in older patients also improves survival and quality of life (QOL) at the cost of an acceptable rate of hospital mortality [1–3]. All investigators who have previously addressed QOL in octogenarians undergoing AVR have examined series of bioprosthesis implantation [1–4], reflecting the common practice of preferential tissue valve choice in patients aged older than 80 years, justified by the general concern of an intrinsic higher risk of bleeding during long-term anticoagulation required for mechanical valves.

In our previous studies, the incidence of anticoagulation-related complications was very low in patients older than 70 years, who underwent mechanical prosthetic implant and whose dicumarol therapy was strictly followed at our dedicated outpatient clinic [5, 6]. Of interest was that the relatively high long-term survival rates in

those series showed that most patients would have likely experienced structural valve degeneration if they had received a bioprosthesis. In the light of our experience with mechanical valve implantation and with the management of oral anticoagulation in septuagenarians, the prolonged life expectancy of elderly AVR patients induces us to admit the use of bileaflet prostheses also in selected octogenarians, with the aim to avoid the risk of a possible reoperation in the ninth decade of life for structural degeneration of bioprosthesis. Hospital mortality of 13% to 25% has been reported for degenerated biologic prostheses replacement in advanced age [7–9].

The aim of this study was to evaluate short- and mid-term results of the implant of biologic and mechanical valves in a population of octogenarians, focusing on the impact on QOL.

## Material and Methods

### Study Population and Prosthesis Selection Criteria

Between July 1992 and September 2006, 160 consecutive octogenarians underwent AVR for aortic valve stenosis at our institution. Patients receiving concomitant coronary artery bypass grafting (CABG) were also enrolled. The study population was divided into two groups: group BP

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Table 1. Preoperative Features of the Study Population

Variable	BP	MP	p Value
Age, mean $\pm$ SD years	82.9 $\pm$ 2.7	81.8 $\pm$ 1.8	0.003
Female sex, %	54.4	58.7	0.59
BSA, mean $\pm$ SD, m <sup>2</sup>	1.68 $\pm$ 0.16	1.7 $\pm$ 0.14	0.33
Atrial fibrillation, %	0	17.4	0.0001
Hypertension, %	66.2	66.3	0.87
COPD, %	32.4	34.8	0.83
Diabetes mellitus, %	26.5	23.9	0.92
CRI, %	2.9	4.3	0.97
NYHA class, %			
II	26.4	25	0.97
III	64.8	66.3	0.98
IV	8.8	8.7	0.79
Ejection fraction	0.526	0.535	0.96
EuroSCORE	6.8	6.2	0.86

BP = biologic prosthesis; BSA = body surface area; COPD = chronic obstructive pulmonary disease; CRI = chronic renal insufficiency; EuroSCORE = European System for Cardiac Operative Risk Evaluation; MP = mechanical prosthesis; NYHA = New York Heart Association.

included patients who received a biologic valve implantation, and group MP included patients who received a mechanical valve.

The choice of the type of valve substitute for an octogenarian patient was fundamentally guided by the consideration of patient's biologic age rather than simply year of birth. We chose mechanical devices for elderly patients who appeared to have a life expectancy of more than 10 years. Patients already receiving long-term anticoagulation for chronic atrial fibrillation (independent of whether cardioversion or surgical ablation of atrial fibrillation was scheduled) were offered a mechanical prosthesis. Biologic prostheses were preferred for those patients with contraindication to oral anticoagulation or those in whom general senescence status or associated multiple noncardiac comorbidities, or both, suggested a life expectancy of less than 10 years. The need for concomitant CABG did not influence the choice of the valve substitute.

Patients who had severe associated diseases causing a very short life expectancy (eg, advanced-stage malignancies) or a longstanding loss of mobility (eg, chronic musculoskeletal diseases or previous cerebrovascular accidents with residual disability), in whom AVR would not have improved QOL, were considered not operable.

This retrospective study was approved by our Institutional Ethics Committee, which waived the need to obtain patient consent. Table 1 reports the preoperative features of the study population.

### In-Hospital Management

All patients received preoperative full cardiologic screening, including transthoracic or transesophageal echocardiography and coronary angiography. Surgical procedures were performed by the same group of surgeons throughout the study period. Anticoagulant therapy was

performed with oral sodium warfarin in all patients, and international normalized ratio (INR) assessment was routinely required daily during the postoperative hospital stay, then weekly until the first postoperative month, and thereafter as indicated by our outpatient clinic, which is completely dedicated to anticoagulation therapy monitoring. Our anticoagulation protocol required a target INR of 2.2 (range, 1.8 to 2.5) for patients with bileaflet prostheses in the aortic position. Patients receiving biologic prostheses were prescribed anticoagulation therapy for 3 months postoperatively if sinus rhythm was maintained.

### Follow-Up Methods

For patients receiving mechanical prostheses, follow-up was mainly conducted on all hospital survivors during our institutional ambulatory activities and was 98.3% complete. Our institution includes an outpatient clinic structure completely dedicated to anticoagulation therapy monitoring, and in which ambulatory INR control is performed 5 days a week. An average of 176  $\pm$  48 blood samples per day are collected from our patients with valve prosthesis. Five nurses are dedicated to blood drawing and a medical team to completing each patient's anticoagulation chart, a document in which the INR value (or earlier, the prothrombin activity), the time between the samples, and the possible complications occurred are noted, by the time of anticoagulation therapy updates. We classified the complications according to the *Guidelines for Reporting Morbidity and Mortality After Cardiac Valvular Operations* proposed by The Society of Thoracic Surgeons [10]. A copy of each chart is left with the patient, and one copy remains in our chart index.

Patients who had undergone biologic valve implantation were prescribed clinical controls at 6-month intervals or shorter intervals, if required. Biologic valve patients were given follow-up charts at discharge similar to those used for patients attending our outpatient clinic, and they and their relatives were recommended to note down every complication that possibly occurred in the time between clinical evaluations. At the scheduled controls, the surgeon reported in an institution's copy of the patient's follow-up chart the complications that occurred. These methods of data collection have allowed for a close contact with the study population, and only 2 patients in group BP were lost at the follow-up by the end of the study.

We have retrospectively entered the anticoagulation results, taken from the ambulatory anticoagulation charts, in an electronic database that also reports every complication that possibly occurred to each patient along with the scores obtained for the Italian version of the Medical Outcome Study Short-Form 36 Health Survey (SF-36) QOL questionnaire. Data for the operation and the early postoperative period were retrospectively collected by hospital chart and outpatient chart review.

### Quality of Life Assessment

Follow-up included the assessment of perceived QOL through the SF-36 [11, 12], which has an established

validity and reliability. The SF-36 questionnaire consists of 36 items grouped into eight domains [13]:

- Physical Functioning (10 items) indicates level of limitations in lifting, bending, kneeling, or walking moderate distance.
- Role-physical (4 items) measures the degree in performing of usual activities for age and social status, such as job and community activities.
- Bodily Pain (2 items) represents the intensity, frequency, and duration of bodily pain and limitations in normal activities due to pain.
- General Health (6 items) is a measurement of perceived overall health, including past and present health.
- Vitality (4 items) measures feeling of energy, fatigue, and tiredness.
- Social Functioning (2 items) indicates ability to develop and maintain mature social relationships.
- Role-emotional (3 items) measures personal feeling of job performance at work or other activities.
- Mental Health (5 items) measures the emotional, cognitive, and intellectual status of the patient.

All SF-36 domains are scaled from 0 to 100 points, with higher scores indicating better-perceived QOL. The mean scores obtained by the two study groups were compared with those of the general Italian population matched for age and sex.

### Statistical Analysis

Continuous data were expressed as mean  $\pm$  standard deviation and compared using the Student *t* test. Discrete variables were compared using the  $\chi^2$  test. Factors significantly associated with adverse outcomes were introduced in a multivariate logistic regression model to identify independent predictors of hospital and long-term mortality. Kaplan-Meier actuarial analyses of survival rates and incidence of valve-related complications were performed. Scores obtained in each of the eight domains of the SF-36 questionnaire were compared by means of paired *t* test between the two groups of the study population as well as with those reported [8] for the age- and sex-matched Italian population. A value of  $p < 0.05$  was considered statistically significant. Data were analyzed using SPSS 13.0 statistical software (SPSS Inc, Chicago, IL).

## Results

### Study Population and Hospital Mortality

The study population consisted of 69 men and 91 women with a mean age of  $82.3 \pm 2.3$  years (range, 80 to 90 years). Group BP comprised 68 patients and group MP had 92. Group BP patients were older, with a mean age of  $82.9 \pm 2.7$ , whereas the mean age of group MP was  $81.8 \pm 1.8$  years ( $p = 0.003$ ). Global hospital mortality was 8.8% (14 patients): 7 patients died in group BP (10.3%) and 7 in group MP (7.6%;  $p = 0.75$ ). The proportion of early cardiac death between the two groups was not statisti-

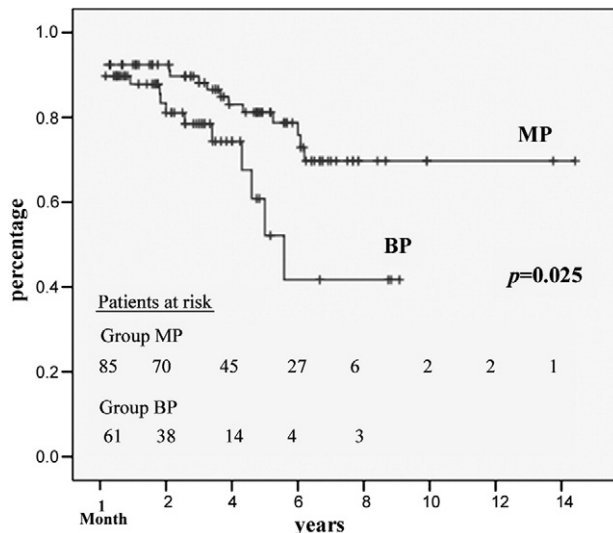


Fig 1. Graph shows actuarial survival as a function of valve type (Kaplan-Meier method) in the groups with biologic prostheses (BP) and mechanical prostheses (MP).

cally different. In group BP, 2 patients died of perioperative myocardial infarction, 1 of low output syndrome, 2 after pulmonary infection, 1 of multiorgan failure, and 1 after a stroke. In group MP, the causes of death were perioperative myocardial infarction in 2 patients and 1 patient each of low output syndrome, pulmonary infection, visceral ischemia, multiorgan failure, and sepsis. In multivariate analysis, only the duration of cardiopulmonary bypass (odds ratio [OR], 1.032; 95% confidence interval [CI], 1 to 1.064) and emergency operation (OR, 8.4; 95% CI, 1 to 74) emerged as predictors of hospital death.

The average postoperative length of stay was  $12.8 \pm 10.5$  days. Nearly all of the octogenarian patients were prescribed a period of postdischarge rehabilitation; however, the actual percentage of patients attending a specialized institution for postoperative rehabilitation was 37.5%.

### Survival and Freedom From Valve-Related Events

During the mean follow-up of  $3.4 \pm 2.8$  years (range, 6 months to 14.4 years), there were 21 late deaths. Causes of death were noncardiac in 61.9%: neoplasm in 5, respiratory failure in 2, cirrhosis in 3, dementia in 1, intestinal occlusion in 1, oldness and generalized decay in 1. The remaining eight late deaths consisted of sudden death in 4 patients, myocardial infarction in 2, stroke in 1, and postoperative death after emergency reoperation in 1 patient with structural bioprosthetic degeneration.

A significant difference emerged in actuarial survival between the two groups. In fact, survival at 1, 3, 5 and 8 years was  $86.4\% \pm 0.04\%$ ,  $76.9\% \pm 0.06\%$ ,  $58.1\% \pm 0.1\%$ , and  $46.5\% \pm 0.14\%$  in group BP, respectively, and  $91.3\% \pm 0.03\%$ ,  $88.6\% \pm 0.03\%$ ,  $81.6\% \pm 0.05\%$ , and  $70\% \pm 0.67\%$  ( $p = 0.025$ ) in group MP (Fig 1). This result could reflect the criteria for choosing a bioprosthesis implant in elderly patients at our institution.



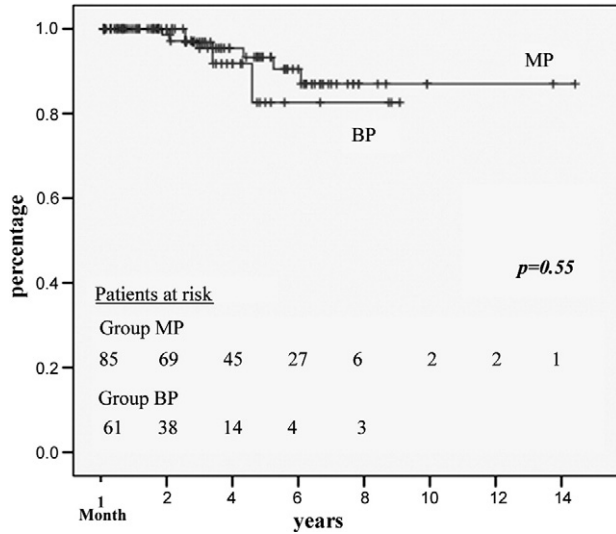


Fig 2. Graph shows actuarial freedom from valve-related complications (Kaplan-Meier method) in the groups with biologic prostheses (BP) and mechanical prostheses (MP).

No statistical difference was found in the 8-year freedom from valve-related complications between group BP and group MP ( $82.6\% \pm 0.1\%$  vs  $87\% \pm 0.053\%$ ,  $p = 0.55$ ; Fig 2). Only one anticoagulant-related hemorrhage was detected in group MP, which was a gastric hemorrhage that was treated with local vasoactive drugs during endoscopy. One ischemic stroke occurred in group BP.

All survivors experienced significant improvements in New York Heart Association functional class compared with preoperative values (1.1 vs 2.8,  $p = 0.0001$ ).

At follow-up, only 3 patients (4.9%) in group BP had atrial fibrillation (at least one episode). Atrial fibrillation has become permanent in 1 patient, who is currently receiving oral anticoagulation (target INR, 2.5).

### Coronary Artery Bypass Grafting Associated With Aortic Valve Replacement

The prevalence of associated CABG did not differ between the two study groups (16.3% in MP vs 22% in BP;  $p = 0.36$ ). Hospital mortality in the patients with associated CABG was 10% vs 8.5% in those without ( $p = 0.79$ ). The impact of associated CABG on long-term survival was similar between patients with isolated AVR and those with concomitant CABG ( $p = 0.34$ ).

### Mismatch

For patients with patient-prosthesis mismatch, in the subgroup of patients (75 in the MP group, 46 in the BP group) with small size prostheses (17, 19, 21 mm), no significant difference was observed between the two groups in terms of mean effective orifice area index ( $0.85 \pm 0.24 \text{ cm}^2/\text{m}^2$  in MP and  $0.82 \pm 0.22 \text{ cm}^2/\text{m}^2$  in BP;  $p = 0.42$ ).

### Quality of Life

A total of 122 patients (97.6% of survivors) satisfactorily completed the SF-36 questionnaire. Scores of the perceived QOL in group BP and in group MP are schematized in Figure 3. Mean QOL scores on each SF-36 scale were satisfactory and comparable in the two groups. Moreover, the scores in seven of the eight domains of the test were significantly higher than those in the general Italian population matched for age and sex; only the vitality domain did not showed a statistical difference.

### Comment

The growing of the number of octogenarians referring to cardiac operations has increased the attention on the outcomes in this subset of patients. A rigorous analysis of an institution's results after AVR in very old patients should focus on three questions:

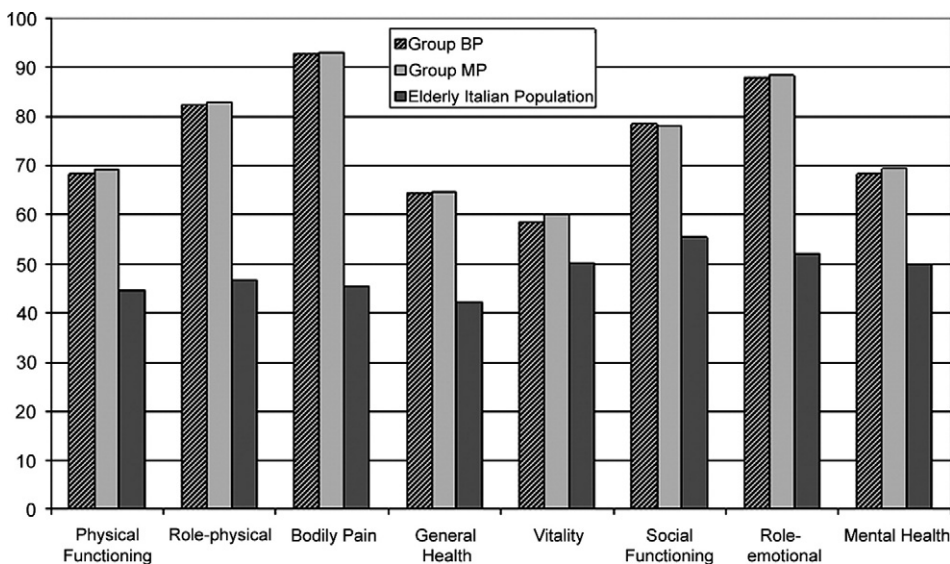


Fig 3. Scores obtained in the eight domains of the Medical Outcomes Study Short-Form 36 Health Survey questionnaire in patients that received biologic prostheses (BP, patterned fill) or mechanical prostheses (MP, light gray fill) compared with the general Italian population (dark fill) matched for age and sex.

1. Do surgical procedures have an acceptable rate of hospital mortality in the 80th decade of life?
2. Are there improvements in survival and QOL after intervention in patients aged 80 years and older?
3. Is there a prosthesis of choice for implantation in octogenarians?

In answer to the first question, many investigators in recent decades have evaluated the feasibility and efficacy of cardiac surgical intervention in very old age [1-3]. Authors reported their experience in AVR in octogenarians with a hospital mortality rate ranging between 4.2% and 14.7% [14, 15]. Reported series show that 30-day mortality lowers with the increasing number of enrolled patients, underscoring the importance of the center's experience. Our series had an acceptable rate of hospital mortality, although it was higher than that observed in younger patients.

As described in "Material and Methods" we consider for surgical intervention octogenarians patients on the basis of their life expectancy and associated diseases. During the last 10 years, with accumulating experience on this subset of patients, we have created selective criteria. Our criteria excluded patients who lacked a self-sufficient life style, were affected by advanced senile dementia, or who presented with severe physical disabilities. We also excluded patients with diseases such as cancer or cerebrovascular accidents with wide diffusely damage.

Numerous articles have reported excellent late survival in this age group [16-20]. Remarkable data were reported by Taylor and colleagues [16], who analyzed the UK Heart Valve Registry data of 1100 patients aged older than 80 years undergoing AVR [16]. The authors found a very satisfactory actuarial survival at 1, 3, 5, and 8 years, with no differences between those receiving biologic and those receiving mechanical prostheses. Similarly, in our study we have obtained a good rate of survival both in patients undergoing bioprostheses and mechanical valve implantation.

The increased life expectancy results in a growing necessity to maintain maximum functioning and independent lifestyle. Health-related QOL is a multidimensional concept based on the patient's perception of his or her health and integrates not only physical functioning but also psychologic status and social dimensions. Standardized questionnaires, especially those self-completed by patients, are a practical, efficacious, and inexpensive method of collecting data. There is a growing interest in the use of health status to evaluate clinical strategies, and because improvement in QOL is considered to be one of the principal goals of valve surgery [3], methods of QOL assessment are increasingly adopted in the clinical research in this field. From reports on postoperative QOL, patients deciding among treatment options may value information about the change in QOL that they can expect after valve surgery. Therefore, QOL needs to be assessed in large and well-defined patient subsets, and it is particularly important to evaluate QOL in elderly patients, who have a higher prevalence of comorbidity, a

more severe surgical stress, and a higher risk of postoperative complications, all factors that may hinder improvement in QOL. Although numerous methods exist for evaluating QOL of patients [21], the validated SF-36 questionnaire [12, 13] is comprehensive yet concise, can be completed in 10 to 15 minutes, and can be administered in person, by phone, or by mail, even in elderly patients [11].

Investigators focusing on long-term outcomes after AVR in octogenarians have reported a positive impact on QOL [15, 20]. Sundt and colleagues [4] described postoperative SF-36 scores in AVR patients aged older than 80 years that were comparable with those of the general elderly population [4]. In the present study, we obtained in seven of the eight domains of the test significantly higher scores than the mean general Italian population matched for age and sex.

When interpreting this result, it should be considered that more than 70% of the patients in our study population were in NYHA functional class III to IV before the operation, so a high percentage of our patients experienced, for a various period of time, a moderate to severe limitation to their daily activity. Symptom relief and the return to previous lifestyle can probably increase the perception of a patient's own health status. Similarly, the Italian general population scores were lower than in our study population because the healthy elderly are prone to compare their current physical and psychologic performances with their youth, with a perceived difference caused by the effects of the aging process itself. Other authors in series of AVR [22] found similar differences between the previously operated on elderly and the age-matched control population, in particular for what concerns the social functioning and emotional domains.

Previous studies have compared the performance of mechanical and bioprosthetic valves on the impact on QOL in young, middle-aged, and septuagenarian patients, reporting similar scores in the various tests used for measurement of perceived QOL between the two valve groups [23, 24]. Our study confirmed a similar impact of the biologic or mechanical prostheses on QOL also in the eighth decade of life.

The ideal valve prosthesis for implantation in octogenarians is still being debated. The increase in long-term survival of the population older than 80 years has increased the risk of reoperation for structural valve degeneration of aortic bioprosthesis in the ninth decade of life [25]. On the other hand, studies have described the safety of oral anticoagulation in elderly patients undergoing mechanical valve implantation [5, 6]. We have confirmed here our previous results testifying to a very low risk of anticoagulation-related complications in elderly patients, focusing in the present study on the octogenarian subset. Our centralized method of monitoring, with the application of a uniform protocol of anticoagulation—in particular, low-intensity anticoagulation for bileaflet aortic prostheses associated with a closer control of the INR—resulted in no increase in the rate of thromboembolic and bleeding events compared with patients with a bioprosthetic valve.

In conclusion, an expert management of dicumarol therapy, with a centralized control associated with a low intensity of anticoagulation, does not increase the risk of thromboembolic or hemorrhagic complications in patients receiving mechanical prostheses. Considering the similar rates of early mortality, the very low rates of valve-related complications in the follow-up with both types of valve substitutes, and the similar perceived QOL, mechanical prostheses and tissue valves can both yield satisfactory results in the difficult setting of the octogenarian patient, and both can be considered in the choice of the valve substitute in this setting. Although the criteria of prosthetic type choice in our experience may have created a bias in favor of the healthier patients receiving mechanical devices, the prevalence of associated comorbidities was not significantly different between the two study groups, encouraging us in our original policy of mechanical implant in selected elderly patients.

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