Quality of Life in Aortic Valve Replacement: Pulmonary Autografts Versus Mechanical Prostheses

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OBJECTIVES
We sought to determine whether the quality of life (QoL) is different in patients after aortic valve replacement with mechanical prostheses or pulmonary autografts.

BACKGROUND
Quality of life after mechanical valve replacement may be affected by the risk of thromboembolism and anticoagulation, and after autograft implantation, by the risk of degeneration and re-operation especially of the homograft.

METHODS
Two groups of 40 patients each—one after the autograft procedure (group I) and one after mechanical valve implantation (group II)—were matched for age, gender and length of follow-up. At latest follow-up, all patients underwent routine echocardiography, the short-form health survey (SF-36) QoL survey and an extensive psychological investigation.

RESULTS
Patients with an autograft showed better QoL scales, as compared with mechanical valve recipients. The difference was significant for both the physical (72.72 ± 20.00 vs. 60.27 ± 26.07, p = 0.021) and psychological health sum scores (74.71 ± 21.03 vs. 64.71 ± 23.49, p = 0.046) and for the subtests of physical functioning (73.72 ± 22.44 vs. 62.77 ± 25.42, p = 0.049), physical pain (88.39 ± 19.13 vs. 73.36 ± 27.08, p < 0.006), general health perception (64.37 ± 17.88 vs. 51.86 ± 22.86, p < 0.008) and health change (61.89 ± 18.94 vs. 50.11 ± 24.37, p = 0.02). The QoL variables did not correlate to pressure gradients, ejection fraction and New York Heart Association functional class. Psychometric tests revealed no meaningful differences between the groups.

CONCLUSIONS
This study provides some evidence that patients with pulmonary autografts have greater benefit in terms of QoL, as compared with recipients of mechanical valve substitutes. (J Am Coll Cardiol 2001;37:1963–6) © 2001 by the American College of Cardiology

Aortic valve replacement is a well-established treatment for aortic valve disease. Conventionally, xenografts or mechanical prostheses are used as substitutes. Mechanical prostheses are easily implanted and durable. Hemodynamic data, however, are suboptimal, and life-long anticoagulation is mandatory, rendering the patient with a constant risk of bleeding and thromboembolism (1,2). Recipients of xenografts usually do not need anticoagulation, but are threatened by the risk of degeneration increasing with time (3,4). Since its introduction by Ross (5), the use of pulmonary autografts for aortic valve replacement (Ross procedure) has been increasingly accepted, because the graft provides ideal properties regarding hemodynamic data, thromboembolism and durability (6).

In contrast to earlier criteria for successful aortic valve surgery (e.g., early and late mortality and absence of major complications), more attention has recently been paid to other outcome variables, such as quality of life (QoL). Quality of life, applied as an indicator of health, is a subjective evaluation of the patients’ state of health and has not been previously investigated in patients who have had the Ross procedure, to the best of our knowledge. The 36-item Short-Form Health Survey (SF-36) (7) is a psychometric test with widespread international use for QoL studies (8,9). Using this test battery, as well as additional psychological tests, we compared patients after aortic valve replacement with pulmonary autografts and mechanical prostheses.

METHODS
Study group. This investigation was performed in patients who had the Ross procedure (mean age 57.58 ± 10.27 years, mean follow-up period 2.21 ± 1.29 years; group I) and in recipients of mechanical aortic valve prostheses (mean age 59.18 ± 10.39 years, mean follow-up period 1.86 ± 0.69 years; group II). Each group consisted of 40 patients, with 29 men and 11 women. The patients’ medical histories (e.g., anemia, angina pectoris, peripheral arteriosclerosis, dyspnea, hypotension, hypertension, diabetes mellitus, claudication, rhythm disorders, rheumatic diseases, partial deafness, stroke, weak eyesight) preoperatively and at latest follow-up were statistically insignificant (p ≤ 0.05). Group I patients exhibited a tendency toward a better, albeit statistically insignificant (p > 0.05), preoperative New York Heart Association (NYHA) functional class. The preoperative left ventricular ejection fraction (EF) was not analyzed, because the groups contained different numbers of patients with aortic insufficiency; therefore, these values are not comparable. Group II patients were under stable anti-
coagulation with phenprocoumon (Marcumar, Roche, Grenzach-Wyhlen, Germany or Falithrom, Hexal, Holzkirchen, Germany). The reasons for choosing the substitute were related to the preferences of the particular surgeon and the referring cardiologist.

**Surgical procedure. GROUP I.** The pulmonary autograft was implanted in the subcoronary position in 30 patients. The full-root replacement technique was performed in two patients, and the cylinder inclusion technique in eight patients. Cryopreserved homografts were used for reconstruction of the right ventricular outflow tract.

GROUP II. Mechanical aortic valves (CarboMedics Canada Ltd., Calgary, Alberta, Canada) were implanted in 31 patients (diameters: 2 × 19, 5 × 21, 12 × 23, 8 × 25, 3 × 27 mm and a 23-mm composite graft), whereas St. Jude Medical valves (St. Jude Medical, Inc., St. Paul, Minnesota) were used in nine patients (diameters: 3 × 21, 3 × 23, 2 × 25 and 1 × 27 mm).

**Study design.** The study was approved by our Institutional Ethics Committee for Human Investigation. Written, informed consent was obtained from each patient. For all patients who underwent the Ross procedure between 1991 and 1997, corresponding mechanical valve recipients were sought in our database. The matching criteria were age, length of follow-up, gender, education and medical history, and malignancies. Forty matched pairs remained. All patients had better values, as compared with the mechanical valve recipients (Fig. 1). The differences were significant for both the physical health sum score (72.72 ± 20.00 vs. 60.27 ± 26.07, p = 0.021) and the psychological health sum score (74.71 ± 21.03 vs. 64.71 ± 23.49, p = 0.046), as well as for the subtests of physical functioning (73.72 ± 22.44 vs. 62.77 ± 25.42, p = 0.049), physical pain (88.39 ± 19.13 vs. 73.36 ± 27.08, p = 0.006), general health perception (64.37 ± 17.88 vs. 51.86 ± 22.86, p = 0.008) and health change (61.89 ± 18.94 vs. 50.11 ± 24.37, p = 0.02). The correlations of the SF-36 scales with EF, pressure gradients and NYHA functional class were not significant for either the patient subgroups or the total group.

**Psychometric questionnaires.** There were no differences between the groups in the 35 scales of the standardized inventories—EBF-24, SFV-66 and FPI-R—except in the FPI-R scales of “health worries” (group I: 7.28 ± 3.55, group II: 8.85 ± 2.78, p = 0.03) and “social desirability” (group I: 5.05 ± 2.72; group II: 3.80 ± 2.72, p = 0.04). In EBF-24, group I had significantly better values in the scale of “physical recovery” (group I: 3.43 ± 1.10; group II: 2.85 ± 1.43, p = 0.05).

**Statistical analysis.** Data were analyzed for each variable by means of the t test or Fisher exact test. Because the groups differed regarding the personality trait of “social desirability,” the SF-36 scales were analyzed by means of analysis of covariance, using the FPI-R scale as the covariate. The data are expressed as the mean value ± standard deviation. Adjusted mean values are reported if analysis of covariance was performed, and p ≤ 0.05 was considered statistically significant. Statistical analysis was performed without alpha adjustments; therefore, the results are considered mainly explorative (14). Correlations were calculated according to Pearson or, in case of ordinal data, Spearman. All statistical analyses were performed with the computer program SPSS for Windows (SPSS version 8.0, SPSS Inc, Chicago, Illinois).

**RESULTS**

The differences between the two groups, in terms of age, follow-up period, gender, education and medical history, were negligible.

**QoL.** For the SF-36 test battery, the patients with autografts had better values, as compared with the mechanical valve recipients (Fig. 1). The differences were significant for both the physical health sum score (72.72 ± 20.00 vs. 60.27 ± 26.07, p = 0.021) and the psychological health sum score (74.71 ± 21.03 vs. 64.71 ± 23.49, p = 0.046), as well as for the subtests of physical functioning (73.72 ± 22.44 vs. 62.77 ± 25.42, p = 0.049), physical pain (88.39 ± 19.13 vs. 73.36 ± 27.08, p = 0.006), general health perception (64.37 ± 17.88 vs. 51.86 ± 22.86, p = 0.008) and health change (61.89 ± 18.94 vs. 50.11 ± 24.37, p = 0.02). The correlations of the SF-36 scales with EF, pressure gradients and NYHA functional class were not significant for either the patient subgroups or the total group.

**Clinical investigation and echocardiography.** Group I patients had a significantly better NYHA functional class than group II patients (class I: 37 vs. 24 patients; class II: 2 vs. 12; and class III: 1 vs. 3; p = 0.004). The EF was significantly higher in group I (63.03 ± 9.2 vs. 52.78 ± 11.85, p < 0.001), with lower maximal and mean pressure gradients across the neoaortic valve (6.15 ± 2.37 vs. 22.83 ± 12.85 mm Hg, p < 0.001; and 3.62 ± 1.40 vs. 13.23 ± 7.28 mm Hg, p < 0.001, respectively). The correlations between EF and these maximal and mean pressure gradients in the total cohort were r = 0.239 (p = 0.019) and r = 0.368 (p = 0.008), respectively. In group I,
no patient had more than trivial aortic regurgitation, except for two patients with mild aortic insufficiency. There was no meaningful mean pressure gradient (6.09 ± 3.14 mm Hg) or insufficiency across the homograft in group I patients. In addition, no irregular valve function or paravalvular leakage was observed in group II patients.

**DISCUSSION**

This study provides evidence that patients who had the pulmonary autograft procedure have greater benefit in terms of QoL, as compared with recipients of mechanical valve prostheses.

**QoL in general.** Aortic valve replacement often results in a substantially improved outcome for severely ill patients. Valve substitutes and therapeutic strategies have significantly progressed in design and function over time. Thus, now, mortality and morbidity are no longer the only criteria for decision-making and for choosing the heart valve substitute; increasingly, other aspects (i.e., QoL) have greater importance. This has not been previously addressed for the pulmonary autograft procedure, especially in comparison to standard mechanical valve replacement. We used the well-validated and often applied SF-36 for the assessment of QoL, which includes four accepted components (15,16): 1) mental state, meaning the emotionality of the patient, with a wide range of aspects like depression, fear and mood; 2) physical state, meaning the patient’s somatic complaints; 3) social relations, meaning its extent of impact on the patient’s state of health and interpersonal relationships; and 4) functional competence, meaning the patient’s mental and physical performance and their capacity to withstand the stress of everyday life. In our study, we found an improved QoL in patients who had the Ross procedure, as compared with mechanical valve recipients. Although the pulmonary autograft is a biologic substitute, it does not seem to be similar to bioprostheses with regard to QoL. Myken et al. (17) could not demonstrate any difference in QoL for patients with bioprostheses versus those with mechanical heart valves, and surprisingly, patients with mechanical heart valves were more concerned about re-operation, as compared with those with bioprostheses. This question of fear of re-operation was not part of our questionnaire, but the patients who had the Ross procedure were thoroughly informed about a possible re-operation, which predominately occurs in the long-term postoperative period. Chambers et al. (18) reported a freedom from re-operation rate of 85% in 25 years. Therefore, the risk of re-operation seems to have no decisive influence on QoL in these patients if the mental health sum scale is considered. Also, the subscales of mental health showed better values in those who had the Ross procedure as compared with those who had mechanical valve surgery (p = NS).

**QoL and left ventricular function.** With regard to the better postoperative EF of the patients with autografts, we
cannot exclude the possibility that the surgeon may have been influenced in his decision about which operative procedure to perform, according to the general preoperative left ventricular function, in the sense that, for the technically difficult and time-consuming Ross procedure, "better" patients had been chosen. In contrast, it is known that the capability of the left ventricle to remodel again is substantially dependent on the hemodynamic characteristics of the valve. Therefore, it is reasonable to assume that the higher EF at follow-up in the patients with autografts, consistent with previous studies (19), reflects, at least in part, the better hemodynamic properties of this graft. However, there were no meaningful correlations of SF-36 scales with either the EF or pressure gradients or NYHA functional class. Thus, the differences in QoL are based on other issues regarding the implanted substitute.

Mental health. Mechanical valve recipients are permanently reminded on their disease by valve sounds, blood sampling for anticoagulation control and life-style and professional limitations, due to bleeding risks, probably leading to an impaired health perception. In addition, the fear of the constant risk of bleeding and thromboembolism may have a negative effect on the mental health of these patients. Whether the valve sound has any effect on the measured subsets is speculative, as Thulin et al. (20) and Myken et al. (17) did not find the valve sound to be a disturbing factor for QoL. In comparison, patients who had the Ross procedure had a significantly increased health perception. Some patients claim to have almost forgotten about their operation. This might also have contributed to their better mental health.

Physical health. A more pronounced difference between patients with autografts and those with mechanical valve surgery was found in our study when physical health was considered. In particular, the subscale of physical pain was significantly improved after the Ross procedure, indicating that these patients feel healthier and notice a benefit from a better function of the autologous pulmonary root in the aortic position. Therefore, it is reasonable to assume that the higher EF initially dependent on the hemodynamic characteristics of the implanted substitute.

Study limitations. This study is not randomized, nor prospective. In addition, there are no ratings of QoL before the operation. Therefore, one cannot finally conclude that group differences in QoL scores are the result of different developments in the two patient groups after their operation. The results reflect differences in the state of QoL nearly two years after the operation in subjects who were carefully matched in terms of age, gender and length of follow-up and who were similar with respect to their preoperative functional state, educational level and psychological traits concerning their personality, as well as several other variables (see Methods section). In particular, the matching of age and gender is important, because these factors have a great impact on the SF-36 score (9). However, these factors must be considered in assessing the results of the study; furthermore, we cannot exclude some bias related to the selection of the operative technique made by the referring physician, which may have some influence on QoL, even two years later.

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