

ORIGINAL ARTICLE

Bioprosthesis versus Mechanical Valve Heart Prosthesis: Assessment of Quality of Life

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Abstract

Background: The aim of this study was to evaluate the QoL of patients undergoing heart valve replacement using the SF-36 questionnaire, compare it between patients with mechanical prosthesis and patients with bioprosthesis, and correlate the results with sociodemographic variables.

Objective: To assess the QoL of patients undergoing heart valve replacement and compare it between patients with bioprosthetic valves and patients with mechanical prosthetic valves.

Methods: We included 36 consecutive patients (16 men) with a mean age of 51 years and six months, who underwent mitral or aortic valve replacement from September 2007 to December 2011. The study was conducted between March and May 2012 and involved the application of the SF-36 survey and a sociodemographic questionnaire. Statistical tests were performed, and data are expressed as absolute frequency and percentile, and median and interquartile range (P25 and P75) (Mann-Whitney test), considering a significance of 95%.

Results: The average time of surgery was 32.5 months (8-61 months). Participants were asked about the practice of physical activity, and 41.7% were physically active. For the SF-36 domains, the highest scores were observed for the social domain whereas the lowest scores were found for mental health, with a mean of 89.25 and 54.44, respectively. In the statistical analysis, we found statistically higher values in emotional functional for patients with mechanical valve prosthesis ($p = 0.0084$).

Conclusion: The QoL of the patients undergoing heart valve replacement improves considerably after the surgery, except for the mental health domain, probably due to the low practice of physical activity. The type of prosthesis seems not to influence the QoL or the patients in the late postoperative period. (Int J Cardiovasc Sci. 2019; [online]. ahead print, PP.0-0)

Keywords: Quality of Life; Sickness Impact Profile; Stress, Psychological; Heart Valve Prosthesis; Mitral Valve; Aortic Valve.

Introduction

Heart valve diseases cause substantial impairment in daily life due to symptoms like angina, dyspnea, and tiredness during normal activities. It is considered a disabling condition as it is one of the main causes of heart failure, with a negative impact on quality of life (QoL).¹ The treatment of heart valve disease is surgical repair or replacement of the affected valve, which can significantly

increase survival and control and reduce the symptoms of the disease.^{1,2}

Despite advances in the development of valvular prosthesis over the years, current devices have some drawbacks, including the need of anticoagulation in patients with mechanical prostheses.³ According to a review conducted in 2011, the choice of the prosthesis should be made with caution, based on the best alternatives for each patient. There is currently no

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valvular prosthesis available with all the characteristics of an ideal prosthesis.⁴

Most complications of valvular prosthesis implantation are probably related to the patient rather than the prosthesis per se.⁵ In recent years, studies on QoL have been one of the main objects of health studies, and has been the focus of discussion forums, lay press, and marketing of products and services.^{6,7}

One of the methods for assessing QoL is the Medical Outcomes Study (MOS) 36-Item Short Form Health Survey (SF-36), which was validated in Portuguese by Ciconelli et al.,⁸ This is a generic tool for assessing QoL, easy to apply and understand and relatively short when compared to others. The instrument can be used in individuals older than 12 years and administered either individually or in groups and evaluate physical and mental health in clinical practice. For each question of the SF-36, a score from 0 to 100 is assigned, where a low score indicates poor health perception, loss of function and pain, and a high score indicates good health perception, preserved function and absence of pain.⁹⁻¹¹

The main of this study was to assess the QoL of patients undergoing heart valve replacement and compare it between patients with bioprosthetic valves and patients with mechanical prosthetic valves.

Methods

The study was approved by the Ethics Committee of the ABC Medical School (approval number 043/2011). Between September 2007 and December 2011, 36 patients underwent mitral and/or aortic valve replacement and were invited to participate in a descriptive study about QoL, using the SF-36 health survey and a sociodemographic questionnaire.

The convenience sample was composed of 16 men and 20 women, consecutively included in the study. All participants signed the informed consent form.

SF-36 health survey

The SF-36 survey is a generic questionnaire that assesses multiple dimensions of health-related QoL, which is widely used due to its high applicability and practicality. It is composed of 36 items grouped in eight scales or domains: functional capacity, physical functioning, pain, vitality, social functioning, emotional role and mental health. Among the 36 items, one item

specifically compares current with previous (one year or more) perception of health status.⁸

Responders are asked to assign a rate from 0 to 100, where 0 denotes the worst health status and 100 denotes the best health status.⁸

Sociodemographic questionnaire

This questionnaire was used to evaluate personal data (age, sex, height, weight, marital status), diagnosis (type of valve replacement), educational background, occupation, risk factors (including chronic obstructive pulmonary disease, COPD, systemic arterial hypertension, smoking and diabetes mellitus) and income of the patients.

All interviews were conducted by the main researcher. The interviews were scheduled individually, by telephone, and lasted approximately 30 minutes.

Statistical analysis

Due to non-normality of data distribution (Shapiro-Wilk test, $p < 0.05$), data were presented as median and 25th and 75th percentiles. The Mann-Whitney test was used for comparisons of independent, quantitative variables between two unpaired samples. All analyses were performed using the Stata 11.0 software package, and significance level was set at 5%.

Results

A total of 36 patients (16 men) were interviewed. Age varied between 19 and 76 years (51.6 ± 15.2 years), 11 were older than 60 years, 14 were aged between 45 and 59 years and the others were younger than 44 years. Almost half of them were overweight (BMI > 25). With respect to educational attainment, 69.44% had some or completed primary education (Table 1).

With respect to the types of surgeries performed, 18 (50%) patients underwent mitral valve replacement, 16 (44.4%) patients underwent aortic valve replacement and 2 (5.6%) underwent mitral and aortic valve replacement, concomitantly. Nineteen patients (52.8%) received bioprosthesis and 17 (47.2%) mechanical prosthesis (%). The causes of valve replacement are described in Table 2. Mean postoperative period, which corresponded to the day of the questionnaire, was 32.5 ± 15.5 months (8 - 61 months).

In our population, 27.8% of patients were working, and 72.2% were retired, out of work or housewives.

Table 1 – Distribution (absolute and relative frequencies) of demographic data by sex

Categories	Variables	Sex					
		Women	%	Men	%	Total	%
Marital status	Single	4	11.11	2	5.55	6	16.66
	Married	9	24.99	13	36.11	22	61.11
	Divorced/separated	4	11.11	1	2.77	5	13.88
	Widow(er)	3	8.33	0	0	3	8.33
	Total	20	55.55	16	44.44	36	100
Education	Illiterate	2	5.55	2	5.55	4	11.11
	Primary	13	36.11	8	22.22	21	58.33
	Secondary and higher education	5	13.88	6	16.66	11	30.55
	Total	20	55.55	16	44.44	36	100
BMI	Normal	6	16.66	6	16.66	12	33.33
	Overweight	8	22.22	9	24.99	17	47.22
	Obesity	6	16.66	1	2.77	7	19.44
	Total	20	55.55	16	44.44	36	100
Age	< 44 years	8	22.22	3	8.33	11	30.55
	45 - 59 years	6	16.66	8	22.22	14	38.88
	> 60 years	6	16.66	5	13.88	11	30.55
	Total	20	55.55	16	44.44	36	100

Table 2 – Distribution of the types and causes of heart valve replacement

Valve replacement	Material	Valve failure	Stenosis	Double replacement	Total
Mitral	Tissue	5	1	1	7
	Metallic	10		1	11
Aortic	Tissue	5		6	11
	Metallic	2	3		5
Mitral + aortic	Tissue		1		1
	Metallic		1		1
Total		22	6	8	36
%		61.1%	16.7%	22.2%	100%

Regarding the family income, 55.6% received less than Brazilian reals (BRL) 1,000; 33.3% gained from BRL 1,000 to BRL 2,000; 8.3% from BRL 2.000 to 3.000; and 2.8% received more than BRL3,000.

All patients reported performing physiotherapy during hospitalization, only 2.8% underwent cardiac rehabilitation in the postoperative period, 100% reported to perform clinical tests periodically and 41.7%

practiced physical exercise regularly, mostly walking, 2-3 times a week.

With respect to the SF-36 domains, the highest scores were found for social functioning (mean of 89.25), and the lowest scores for mental health (mean of 54.4). Comparisons of SF-36 results and sociodemographic data between mechanical prosthetic valves and bioprostheses are found in Table 3.

Comparison of SF-36 scores by the type of prosthesis implanted showed that emotional functioning scores were significantly higher in the emotional functional domain for patients with mechanical prosthesis compared with those with bioprosthesis (0.0084) (Table 3). In the analysis by valve replaced, patients with aortic valve replacement showed significantly higher scores for the functional capacity domain ($p = 0.0047$). In addition, significantly higher scores were found in the functional capacity domain for men compared with women ($p = 0.0264$). Considering the marital status, married patients showed significantly higher scores in the general health ($p = 0.0287$) and social functioning ($p = 0.0063$) domains compared with single patients.

Regarding the income of participants, those who received more than BRL1,000 showed significantly higher mean scores for the pain ($p = 0.0375$) and general

health (0.0078) domains. Working patients showed significantly higher scores in functional capacity ($p = 0.0112$) compared with non-working patients. Finally, considering physically active versus physically inactive individuals, mean scores of physical functioning ($p = 0.0385$), general health ($p = 0.0371$) and social functioning ($p = 0.0069$) domains were significantly higher in physically active individuals.

No difference in SF-36 scores was found between individuals according to race/ethnicity, educational attainment, age, or BMI.

The item of the SF-36 questionnaire that compares current QoL of patients with the QoL one year before showed that, as compared with the QoL one year before, 22.2% of the patients reported that current QoL is much better; 33.33% a little better and 36.1% reported that current QoL is almost the same; 8.33% a little worse, and 0% much worse.

When analyzed by gender, in general, male patients reported a better QoL – 62.5% of men reported that current QoL is a little or much better than one year before. When analyzed by the type of valve implanted (mechanical vs. bioprosthetic valves and aortic vs. mitral), patients with bioprosthesis and patients with aortic prosthesis referred a better QoL nowadays compared with one year before.

Table 3 – Comparison between mechanical and bioprosthetic valves of the SF-36 scores in each domain

Domain	Type of prosthesis						P
	Mechanical			Bioprosthesis			
	Median	25 th percentile	75 th percentile	Median	25 th percentile	75 th percentile	
Functional capacity	65	55	75	75	60	80	0.12
Physical functioning	75	75	100	100	75	100	0.46
Pain	84	62	84	84	62	100	0.59
General health	72	67	82	72	62	82	0.93
Vitality	70	65	75	70	60	75	1
Social functioning	100	75	100	100	75	100	0.44
Emotional functioning	100	100	100	67	67	100	0.0084*
Mental health	60	52	60	56	44	60	0.66

*Mann-Whitney test; *p < 0.05.*

Discussion

The results of the present study indicate that the patients undergoing heart valve replacement reported a satisfactory QoL according to the scores achieved in most of the SF-36 domains. Similar findings were reported by Grady et al.¹¹ that evaluated 2,524 patients undergoing several cardiac surgeries and showed that the QoL of patients undergoing replacement of heart valve improved from baseline to six months after surgery and remained relatively stable through 3 years. This result demonstrates that the QoL of these patients markedly improves after valve replacement surgery compared with the preoperative period.

Except for the SF-36 domains functional capacity, physical functioning and mental health, the SF-36 scores of our population were similar to the mean scores obtained from residents of Sao Paulo city, previously published.¹² This is in agreement with another study showing that patients undergoing cardiac operations reported comparable or even higher SF-36 scores compared with the general population of the same area.¹¹

In the analysis of the type of heart valve implanted (biological versus mechanical), we found a statistically significant difference only for the emotional functioning domain ($p = 0.0084$). Vicchio et al.,¹³ also concluded in a study about the QoL of octogenarians who had undergone heart valve replacement that the type of the valve had no influence on their QoL.

In addition, our results were similar to those reported in a study that evaluated the QoL of 136 patients assessed two years after aortic valve replacement. The authors compared the QoL of patients with bioprostheses and patients with mechanical prostheses and found no statistically significant difference.¹⁴ Compared with this study, our group reported higher mean scores for all SF-36 domains, except for mental health and pain.

In the mental health domain, which encompasses depression and anxiety, we found low scores, with a mean of 54.44. These data seem to differ from the results of Aboud et al.,¹⁴ who observed higher scores in a study with a similar sample (mean of 69.6). However, our results seem to be not that different considering the mean age of our sample, 51 years and 6 months old, and considering that most of our sample had a bioprosthesis, since the mean score in the mental health domain in the equivalent group was 56.

According to Ruo et al.,¹⁵ depression and anxiety were found in 20% of the patients with coronary artery disease.

The authors suggested that efforts should be made in the treatment of depression and anxiety in cardiac patients. Although we studied a different population, heart valve replacement surgery can also have a negative impact on the perception of health and performance of physical exercise, leading to worsening physical impairment and QoL, similarly to what was reported by Ruo et al.¹⁵

The low score in health perception may be explained by the fact that many patients feel frustrated for not performing all the activities they wished to do, since expectations in the postoperative period may be high. Góis et al.,¹⁶ support this theory in the study about QoL in the pre and postoperative periods of myocardial revascularization to explain the deterioration in social functioning and mental health.

These low scores can also be explained by the lack of physical activity, as 58.3% of the patients were physically inactive, which can have a negative impact on the QoL, on emotional status and on health. The positive impact of physical activity was well demonstrated in our study, as we found a statistically significant difference in three of the eight domains of the SF-36 questionnaire. Physically active individuals had better scores compared with physically inactive ones.

Exercise increases work capacity and improves the QoL.¹⁷ Araújo et al.,¹⁸ showed that physical activity has a positive effect on emotional health. Veigas & Gonçalves,¹⁹ in a study on 207 individuals, reported the impact of physical activity on anxiety and stress in younger individuals and on depression in older individuals. The incidence of these conditions was lower in physically active than inactive ones.

In addition, a considerable number of patients reported to be unsatisfied with the fact that they did not return to work and to feel insecure to perform activities that require greater effort. These findings are in accordance with another study²⁰ on acute myocardial infarction patients which reported that an inability to return or be fit for work had a negative influence on QoL.²⁰

The present study has some limitations including the different periods of time from the surgery between the patients and lack of information of ventricular function, which may have had some influence on the QoL. Also, the sample size was small due to the low adherence to the treatment by the patients during the study period.

In the present study, patients undergoing aortic valve replacement showed better scores in functional

capacity as compared with those undergoing mitral valve replacement (73.12 and 64.16, respectively, $p < 0.05$). This difference may be related to the prevalence of male patients in the aortic valve replacement group, considering the greater physical capacity of men compared with women.

Conclusion

The QoL of the patients undergoing heart valve replacement improves considerably after the surgery, except for the mental health domain, probably due to the low practice of physical activity. The type of prosthesis seems not to influence the QoL of the patients in the late postoperative period.

Author contributions

Conception and design of the research: Molero Junior JC, Breda JR. Acquisition of data: Molero Junior JC, Breda JR. Analysis and interpretation of the data: Molero Junior JC, Raimundo RD, Amaral JAT, Abreu LC, Breda JR. Statistical analysis: Raimundo RD, Amaral JAT, Abreu LC, Writing of the manuscript: Molero Junior JC, Raimundo RD, Abreu LC, Breda JR. Critical revision of the manuscript for intellectual content: Molero Junior

JC, Raimundo RD, Amaral JAT, Abreu LC, Breda JR. Supervision / as the major investigator: Breda JR.

Potential Conflict of Interest

No potential conflict of interest relevant to this article was reported.

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Study Association

This study is not associated with any thesis or dissertation work.

Ethics approval and consent to participate

This study was approved by the Ethics Committee of the *Faculdade de Medicina do ABC* under the protocol number 043/2011. All the procedures in this study were in accordance with the 1975 Helsinki Declaration, updated in 2013. Informed consent was obtained from all participants included in the study.

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