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Evaluation of patients' quality of life aspects after cardiac pacemaker implantation

Avaliação de aspectos da qualidade de vida em pacientes pós-implante de marca-passo cardíaco

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Abstract

Objective: **To evaluate patients' quality of life aspects after pacemaker implantation, relating it to gender, age, and implantation timespan.**

Methods: **A total of 107 clinically stable patients of both genders (49.5% women and 50.5% men) over 18 years old (average 69.3±12.6 years) and presenting an implantation timespan of three to 12 months (average 6.36±2.99 months) were evaluated. The evaluation included personal, clinical, and implant data as well as quality of life questionnaires (AQUAREL and SF-36). Statistical analysis was conducted using the t test and Pearson correlation. with a 5% significance level.**

Results: **The lowest SF-36 score referred to physical aspects, and the highest score referred to social aspects. In AQUAREL. the lowest score referred to dyspnea, and the highest referred to discomfort. There was a significant association between gender and quality of life in SF-36 (physical functioning and emotional aspects) and in AQUAREL (dyspnea). A negative correlation was observed between age and quality of life (functional capacity in SF-36, and discomfort in AQUAREL) in relation to implantation timespan, a correlation with vitality from SF-36.**

Conclusion: **Lower quality of life scores were found in physical aspects and dyspnea; and higher scores in social aspects and discomfort. Men presented higher quality of life scores related to physical functioning, emotional aspects and dyspnea. As age increases, quality of life worsens regarding functional capacity and discomfort; and the longer the pacemaker implantation timespan, the worse quality of life when it comes to vitality. Gender, age, and implantation timespan influence quality of life; thus, these variables must be considered in strategies for improving quality of life of patients with pacemakers.**

Descriptors: **Quality of Life. Indicators of Quality of Life. Pacemaker. Artificial.**

Resumo

Objetivo: **Avaliar aspectos da qualidade de vida em pacientes pós-implante de marca-passo e relacionar com gênero, idade e tempo de implante.**

Métodos: **Foram estudados 107 indivíduos de ambos os gêneros (49,5% do sexo feminino e 50,5% do sexo masculino),**

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Abbreviations. acronyms & symbols	
AQUAREL	Assessment of QUality of life And RELated events
PM	Pacemaker
QoL	Quality of life
SF-36	Medical Outcomes Study 36-Item Short-Form Health Survey
SUS	Unified Health System

tempo de implante três a 12 meses (média de 6,36±2,99 meses), estáveis clinicamente com idade acima de 18 anos (média de 69.3±12.6 anos). A avaliação constou de: dados pessoais, clínicos, do implante e questionários de qualidade de vida (AQUAREL e SF-36). Análise estatística empregou teste t e correlação de Pearson, com significância de 5%.

Resultados: **No SF-36, o menor escore ocorreu no domínio aspectos físicos e, o maior, em aspectos sociais. No AQUARE, o menor escore foi em dispneia e o maior em desconforto. Verificou-se associação significante entre gênero e qualidade de vida no SF-36 (capacidade funcional e aspectos emocionais) e no AQUAREL (dispneia). Observaram-se correlações negativas entre idade e qualidade de vida (capacidade funcional do SF-36 e em desconforto do AQUAREL) em relação ao tempo de implante, correlação com vitalidade do SF-36.**

Conclusão: **Menores escores de qualidade de vida foram encontrados em aspectos físicos e dispneia; maiores em aspectos sociais e desconforto. Homens apresentaram maiores escores de qualidade de vida em capacidade funcional, aspectos emocionais e dispneia. Conforme aumenta a idade, pior é a qualidade de vida em capacidade funcional e desconforto, e, quanto maior o tempo de implante de marca-passo, pior a qualidade de vida em vitalidade. Gênero, idade e tempo de implante influenciam na qualidade de vida, dessa forma. essas variáveis devem ser consideradas nas estratégias para melhora da qualidade de vida em portadores de marca-passo.**

Descritores: **Qualidade de Vida. Marca-Passo Artificial. Indicadores de Qualidade de Vida.**

INTRODUCTION

The use of artificial heart stimulation as treatment for cardiac conduction disorders is a challenge that seeks to add quality to the change in prognosis of patients with heart disease. The technology of current devices provides several resources, which can be adapted to the needs of every patient, making it possible to improve quality of life (QoL) [1-3].

The pacemaker (PM) is a resource for artificial cardiac stimulation that favors many patients with heart disease who have atrioventricular blocks in correcting heart rhythm disorders and atrioventricular synchrony [4]. There have been many PM implantations worldwide, and records from the 11th World Survey of Cardiac Pacing and Implantable Cardioverter-Defibrillators: Calendar Year 2009 show that there were 136 PM implantations per million inhabitants in Brazil [5].

Following the advances and the performance of the medical field. several studies have been carried out in order to assess QoL as well as recognize the importance of the patient's point of view on his disease and the importance of monitoring the quality of therapeutic measures [6-9]. Thus, assessment of QoL associated with health refers to the patient's subjective viewpoint on his health, which can be in conflict with physiological evaluations, interpretations of his well-being, and physical functioning, but it can also broaden the clinical parameters [6,9]. In this sense, the World Health Organization defines QoL as "individuals' perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations,standards and concerns" [10].

Several instruments have been suggested to assess health-related QoL. There are generic instruments, non-specific to a single disease and better suited for epidemiological studies, and instruments for specific diseases, which are clinically more sensitive to detect alterations related to the disease [9]. For patients with PM, literature recommends the use of a specific questionnaire coupled with general questions about health from a generic questionnaire [11]. Stofmeel et al. [11-13] developed and presented a questionnaire specifically for patients with PM, the Assessment of QUality of Life And RELated Events (AQUAREL), which should be used as an extension of the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) questionnaire [7].

A number of studies have used those instruments in assessing QoL of patients with PM. However, they have proved insufficient to determine how PM therapy interferes in the patient's life. Their effectiveness in improving survival is clearly seen, yet there is still concern about evaluating and monitoring the clinical and psychological consequences of the therapy. Patients undergoing PM therapy can suffer changes in different aspects of their lives: physical, social, emotional, and psychological [14]. Investigating the patient

with PM's perception of his QoL can help direct the interpretations and analysis of the treatment's effectiveness, which justifies the importance of this study.

Given the above, this study set out to assess the perception of QoL of patients with definitive PM and its association with gender, age, and implantation time span.

METHODS

A descriptive, quantitative, cross-sectional, observational study was carried out in patients with PM during follow-up at the Cardiac Surgery and Pacemaker Department at Santa Casa de Misericórdia in Marília, SP. Data was collected from August 2009 to June 2010.

Minimum sample was estimated at n=85, considering a significance level of 5% (α=0.05), a type II error of 20% (β=0.20), and effect size $|r|$=0.30 [15].

The study had been previously approved by the Ethics Committee of the Marília Medical School (FAMEMA), protocol nº442/08. All volunteers provided written informed consent.

Clinically stable patients of both genders aged 18 and older, within three and 12 months of PM implantation, and who provided written informed consent, were included in the study. Patients excluded were the ones who did not understand the test sequence; were speech, hearing or mentally impaired; or did not wish to participate in the study.

Volunteers were assessed using a protocol developed by the researchers according to the literature [16,17], which included: personal data, vital signs, background, and questions related to the PM. In addition, specific tests were also performed, such as functional class according to Goldman's Specific Activity Scale [18,19] and QoL questionnaire.

The assessment of QoL was made by applying AQUAREL, a QoL questionnaire specifically designed for patients with PM, which must be used with the SF-36 generic questionnaire [11,13]. Both instruments. AQUAREL and SF36, have been translated and adapted to Portuguese, validated, and had their reliability and reproducibility well-established in the Brazilian population [7,17].

AQUAREL consists of 20 questions divided into three domains: chest discomfort (corresponding to questions 1 to 6, about chest pain, and questions 11 and 12, about dyspnea at rest), arrhythmia (corresponding to questions 13 to 17), and dyspnea on exertion (corresponding to questions 7 to 10, about dyspnea on exertion, and questions 18 to 20, about fatigue) [16].

Every domain has specific items with five response categories, with values ranging from 1 to 5. Individual scores obtained for each of the domains were added up and computed using the formula shown in Formula (1). Final scores can range from zero (all complaints) to 100 (no complaints), where a score of 100 represents perfect QoL [7,12].

The scores of the three domains of the AQUAREL QoL questionnaire (chest discomfort: questions 1 to 6, 11 and 12; dyspnea: questions 7 to 10, 18 to 20; arrhythmia: questions 13 to 17) were calculated using Oliveira's [16] Formula (1), where equivalence between the letters of the answers for items of every question in the AQUAREL questionnaire and the 5-point Likert scale was: a)=5; b)=4; c)=3; d)=2 e e)=1.

Formula (1):

$$\text{Score} = 100 - \{[(\Sigma N - n°N) / (n°N \times 5) - n°N]\} \times 100$$

Where: ΣN = sum of points from questions that comprise the score

n° N = number of questions that comprise the score

SF-36 consists of questions divided into eight domains: physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional, and mental health [17].

The AQUAREL and SF-36 questionnaires were applied in the form of interviews by a previously trained interviewer. Sum of the points was done according to what has been described in the literature for each of the questionnaires and the domains were graded by a specific calculation ranging from 0 to 100. A low numeric score reflects poor health perception, loss of function, and presence of pain whereas a high numeric score reflects good health perception, preserved function, and absence of pain [16,19]. Therefore, a cut-off point of 50 (mean score) was established to determine the best and worst domains. Domains with scores lower than 50 represent worse QoL and those with scores 50 or over represent better QoL [20,21].

Statistical analysis

Data were summarized using tables. absolute frequency, percentages, means, standard deviation, and minimum and maximum values. In order to assess the relationship between gender and the SF-36 and AQUAREL domains, the following tests were used: t test for independent samples and one-way ANOVA for three or more independent groups complemented by Tukey's HSD multiple comparison test for statistically significant results as indicated by the ANOVA test, Pearson correlation coefficient (r) was used to analyze the correlations between quantitative variables [22]. A 5% level of probability of rejecting the null hypothesis was set for all tests.

RESULTS

A total of 107 patients of both genders participated in the study, where 49.5% were female and 50.5% were male ranging from 29 to 90 years old. Mean period after PM implantation was 6.36±2.99 months and mean age was 69.3±12.6 years. In terms of profession. most were retired citizens (43%), followed by 31.8% of homemakers. There were 12.1% of the patients with Chagas disease; 64.5% with systemic arterial hypertension; 24.3% with diabetes mellitus;

48.6% of non-smokers; and 38.3% with some kind of sleep disorder. Patient characteristics and type of intervention are summarized in Table 1.

One-way ANOVA (significance level of 5%) showed significant differences between perceptions of the respondents (AQUAREL and SF-36) in terms of implantation time span. according to the following groups: G1 – implantation time span of three months or less; G2 to G10 – implantation time span of 4, 5, 6, 7, 8, 9, 10, 11, and 12/13 months, respectively. All of the results were non-significant (P>0.05), i.e., there were no significant differences between at least two of the groups, which allowed for the creation of one single group in terms of implantation time span for the assessment of respondents' perception using the AQUAREL and SF-36 questionnaires.

Table 2 shows the scores of the AQUAREL QoL questionnaire obtained from the total sample and comparison according to gender. A significant result was observed in the dyspnea domain.

Table 3 shows data from the evaluation of the SF-36 QoL questionnaire obtained from the total sample and comparison according to gender. Significant results were observed in the physical functioning and role-emotional domains.

The results of the study indicate a significant positive correlation between AQUAREL chest discomfort domain and age. There was no significant correlation between age and the remaining domains. In terms of implantation time span, there was no correlation with QoL according to AQUAREL (Table 4).

Table 1. General and clinical characteristics of the 107 patients included in the study.

Variables	n	%
Gender		
Female	53	49.5
Male	54	50.5
Education		
Illiterate	33	30.8
Basic education – incomplete	59	55.1
Secondary education – incomplete	2	1.9
Secondary education – complete	8	7.5
Tertiary education	4	3.7
Chagas disease		
Yes	13	12.1
No	94	87.8
Indication for implantation		
Atrioventricular block	62	57.9
Sinus node syndrome	30	28.0
Other	15	14.1
Type of stimulation		
Bicameral	93	86.9
Unicameral	14	13.1
Implantation time span (months)		
Mean (standard deviation)	6.4±3.0	
Minimum – Maximum	1 - 13	
Functional class		
Class I	74	69.2
Class II	8	7.5
Class III	23	21.5
Class IV	2	1.9

Table 2. Mean values for quality of life from the AQUAREL questionnaire for full sample and comparison of domains according to gender (t test).

Gender	Chest Discomfort	Dyspnea	Arrhythmia	Total AQUAREL
Full sample	90.8 ± 14.9	75.0 ± 21.3	89.0 ± 14.1	84.9 ± 13.9
Male	90.6 ± 13.2	79.1 ± 18.3	90.4 ± 13.6	86.7 ± 13.1
Female	91.0 ± 16.6	70.8 ± 23.3	87.6 ± 14.6	83.1 ± 14.6
t test (P value)	P=0.887	P=0.044*	P=0.306	P=0.187

** Significant (P<0.05)*

Table 3. Mean values for quality of life from the SF-36 questionnaire for full sample and comparison of domains according to gender (t test).

Gender	Physical Functioning	Role-Physical	Bodily Pain	General Health	Vitality	Social Functioning	Role-Emotional	Mental Health
Full sample	69.2 ± 24.9	58.4 ± 37.6	63.5 ± 27.0	72.4 ± 23.6	74.2 ± 20.6	89.1 ± 21.8	62.6 ± 43.1	74.0 ± 23.0
Male	75.8 ± 20.9	60.6 ± 36.5	66.5 ± 28.5	74.5 ± 20.4	75.7 ± 20.3	91.8 ± 20.4	71.6 ± 37.9	77.6 ± 21.5
Female	62.5 ± 27.0	56.1 ± 38.8	60.5 ± 25.2	70.2 ± 24.0	72.7 ± 20.9	86.3 ± 23.0	53.4 ± 46.3	70.3 ± 24.2
t test (P value)	P=0.005*	P=0.537	P=0.255	P=0.352	P=0.454	P=0.189	P=0.029*	P=0.103

** Significant (P<0.05)*

Table 4. Pearson correlation coefficient and *P* value between score values of AQUAREL questionnaire domains and age and implantation time span.

	Chest Discomfort	Dyspnea	Arrhythmia	Total AQUAREL
Age	r=0.197*	r=0.013	r=0.024	r=0.085
Implantantion	*P*=0.042	*P*=0.895	*P*=0.807	*P*=0.385
time span	r=-0.016	r=-0.103	r=0.039	r=-0.045
	P=0.872	*P*=0.289	*P*=0.663	*P*=0.645

** Significant (P<0.05)*

Table 5. Pearson correlation coefficient and *P* value between score values of SF-36 questionnaire domains and the variables: age and implantation time span.

	Physical Functioning	Role-Physical	Bodily Pain	General Health	Vitality	Social Functioning	Role-Emotional	Mental Health
Age	r =- 0.338	r=0.074	r=-0.118	r=-0.094	r=-0.014	r=-0.078	r=-0.022	r=0.073
Implantantion	*P*<0.001*	*P*=0.447	*P*=0.226	*P*=0.337	*P*=0.886	*P*=0.422	*P*=0.821	*P*=0.456
time span	r=-0.095	r=-0.098	r=0.040	r=-0.095	r=- 0.193	r=0.089	r=0.118	r=-0.049
	P= 0.330	*P*=0.315	*P*=0.679	*P*=0.328	*P*=0.046*	*P*=0.362	*P*=0.226	*P*=0.615

** Significant (P<0.05)*

In addition, there was negative correlation between the SF-36 physical functioning domain and age. In terms of implantation time span, a negative correlation was observed with the SF-36 vitality domain. There was no significant correlation between age and implantation time span across the remaining domains (Table 5).

DISCUSSION

Data for this study was collected in a single interview within a mean time span of six months after implantation. The lack of a preoperative evaluation as a control group may be questioned; however, recent data, such as those published by Gomes et al. [23], have systematically shown that preoperative QoL evaluation is lower than the postoperative one. Another point worth mentioning is the characteristics of the Department where the study was carried out. The Department is a reference for the Unified Health System (SUS) of the Regional Health Division IX, based in Marília and comprising 62 municipalities in the state of São Paulo.

Thus, a large number of these patients are referred for emergency treatment, with stimulation being provided by a temporary PM and in need of immediate surgery, due to the difficulty of finding vacant beds in the system and, at times, the impossibility of immediate transfer to our Department. Under these circumstances, we chose to assess QoL of our population of patients as well as their perception of this condition at a specific time after implantation.

The importance of assessing QoL in health-related outcomes is now well known and accepted. Most of the studies aimed at evaluating the results of treatments evaluate QoL from the patient's perspective as well [6,14,17]. The patient's perception of his own health and QoL have emerged as references for learning how the patient perceives the treatment being received. It is important to consider that advances in the medical field often allow interferences in the natural progression of diseases and, in some cases, in the complex patient-disease relationship. The question is whether we are adding life to the years or just prolonging an unsolvable medical condition. In the words of Nobre [24], "QoL has become increasingly more valued than extending life under limited or disabled conditions".

Concepts of dysthanasia and orthotanasia, now regulated by decree from the Federal Council of Medicine, make us ponder the use of techniques to prolong life of patients with incurable diseases. Indication of artificial stimulation cannot be a matter of artificial life support without expectation of cure neither of controlling morbid conditions

[25]. In the past 25 years, artificial cardiac stimulation has gone through a fast and striking modernization process of its equipment (*hardware* and *software*). The miniaturization of generators achieved by the incorporation of circuits that use computer-derived language and technology coupled with increasingly efficient and reliable electrodes have allowed any patient to be artificially stimulated. whether temporarily or permanently. As a result, we are able to change the natural history of patients with heart conduction disorders [14].

The application of QoL questionnaires in patients with PM has proved to be of great use in evaluating the results of this type of treatment [8,11,12].

In terms of QoL assessment using the AQUAREL and SF-36 questionnaires, they both have final scores ranging from 0 to 100, thus, a cut-off point of 50 (average score) was established to determine the best and worst domains [20]. Domains with scores lower than 50 were classified as having lower QoL and those with scores of 50 or over as having good QoL [16,20].

In this sense, none of the domains obtained scores lower than 50, indicating that QoL of patients after implantation is above average. Therefore, we can state that, overall, the QoL perceived by these patients was good. corroborating the findings of Brasil [3] and Gomes et al. [23].

Analyzing the highest and lowest scores across the domains assessed by the SF-36 questionnaire, we found the worst result in physical functioning (58.4), followed by role-emotional (62.6), and the best result in social functioning (89.1). Since the lowest scores show poor health perception. we can say that, in the evaluation made by SF-36, our population has a poor assessment in terms of physical functioning, similar to the findings of [26], however, above those of Oliveira [16], which showed the worst QoL for role-emotional (46.7), followed by physical functioning (51.4), and the best quality in social functioning (74.3).

In terms of social functioning. which reflects the ability to have relationships in addition to a few emotional aspects, we found perception of improvement, confirmed by the high score. According to SF-36, our patients showed better perceptions in the mental functioning domain compared to physical functioning. contrary to the findings of Gomes et al. [23], which stated a reduction in scores of the social functioning and role-emotional domains after PM implantation.

The same correlation is seen when the results of physical and social functioning are confronted with the findings published by van Eck et al. [27], comparing the scores in patients waiting for PM implantation with a control population (no indication for PM) belonging to the same age group. There is no change in the components of the physical functioning domain before and after implantation; however, in the mental functioning domain, the difference is significant, presenting better scores after implantation.

We applied the AQUAREL questionnaire to the same population and results showed the lowest score for dyspnea (75.0) and the highest for discomfort (90.8). These findings corroborate with the study performed by Oliveira [16], who assessed QoL (AQUAREL and SF-36) in 139 patients with PM and observed lower QoL according to AQUAREL for dyspnea (75.3) and better for discomfort (85.3).

Cesarino et al. [28] studied QoL in 50 patients with implantable cardioverter-defibrillator (ICD) using the SF-36 questionnaire. The social functioning domain had the highest score (80.5) and physical functioning. the lowest (40.5), in agreement with our study.

When analyzing gender, significant results were found in the physical functioning and role-emotional domains. using SF-36, with women at a disadvantage. Nowak et al. [29] suggest that there is a delay in the indication of PM in women compared to men. The prevalence of atrioventricular blocks in male patients means that indication of artificial stimulation is more commonplace and it happens earlier for these patients. According to the authors, the same is seen in European records, leading to differences in the age of patients at the time of first implantation as well. This late indication in female patients might account for the difference observed in the QoL evaluation across gender. Women who undergo the surgery are already at a more advanced stage of the disease. As far as AQUAREL, significant results were also found in the dyspnea domain, which is related to symptoms associated with physical capacity, with women at a disadvantage. Brasil [3] observed non-significant results when comparing QoL (using the QoL index) in terms of gender, both before and after permanent PM implantation.

Furthermore, we attempted to correlate the QoL variables obtained from applying both questionnaires with age and PM implantation time span. According to Cunha et al. [18], the literature shows controversial results concerning the correlation between age and QoL in different populations [13,23,30]. Nevertheless, the literature also indicates that age is related mainly to variables associated with the physical condition of patients [17,30,31].

In our study. in accordance with van Eck et al. [27], one of the most important predictors of QoL after implantation is age, which is inversely related to QoL, findings that are similar to those of Cunha [18] and Gomes et al. [23]. Our population is older (69.3 years) than others, as evaluated by Oliveira et al. [32] with a mean age of 60 years. In the population evaluated by Oliveira et al. [32], the worsening in functional class was the determining factor in lower QoL.

When we performed this analysis using SF-36, we observed a negative correlation between age and physical functioning. This domain indicates how much health affects routine activities. Older patients per se show more difficulty performing the activities evaluated in this domain. Similar to

our findings, Cunha et al. [18] observed a negative correlation between age and SF-36 physical functioning domain. On the other hand, they also found correlation between age and role-emotional, adding to the controversial question of the relationship between age and QoL.

However, Cesarino et al. [28], in a study about QoL perception (SF-36) in patients with ICD, found no statistically significant difference between QoL and age. Two studies developed in the countryside of Goiás also found no significant association between QoL scores and age: Gomes et al. [23] assessed QoL (AQUAREL and SF-36) after PM implantation in 23 patients and Antônio et al. [33] evaluated QoL (SF-36) in 25 patients with heart disease who were eligible for PM implantation at a hospital.

Age is one of the factors we cannot interfere with when we find more frequent and more severe cardiovascular diseases since it is part of a non-modifiable risk factor (ageing). Even though it is known that PM implantation can benefit QoL, at times, this cannot be measured in elderly populations because of other coexisting diseases and lower life expectancy [3,26].

There was also negative correlation between implantation time span and vitality when evaluated by SF-36. The vitality domain is included in the mental functioning dimension of SF 36. It evaluates daily situations that involve physical capacity characteristics related to anxiety and depression. In our findings, time span after implantation is associated with lower vitality. Studies about this association could not be found and we credit this association to the average age of the patients evaluated, as discussed in terms of physical functioning.

These results enable us to evaluate our population of patients with PM and contribute to further increase indications of this technique so that the results can truly benefit patients. Patients had adequate perceptions of their QoL with the use of the AQUAREL and SF-36 questionnaires. The use of the AQUAREL and SF-36 questionnaires is feasible, being a good complement to patients with PM.

CONCLUSION

According to the results. we can conclude that QoL of patients with PM is worse in terms of physical capacity and dyspnea and better in terms of social functioning and discomfort. Male patients showed better QoL in the physical functioning, role-emotional, and dyspnea domains, when compared to female patients. As age increases, QoL becomes worse in terms of physical functioning and discomfort, and the longer the PM implantation time span. the worst QoL in terms of vitality.

Gender, age, and implantation time span exert influence on QoL, thus, these variables should be considered in the strategies used to improve QoL of patients with PM.

Authors' roles & responsibilities	
RTB	Data collection. analysis. and interpretation; writing of the manuscript
SMRC	Study design; data analysis and interpretation
MAMS	Writing of the manuscript
JBCB	Data collection. analysis. and interpretation; writing of the manuscript

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