

Correlation between quality of life, functional class and age in patients with cardiac pacemaker

Correlação entre a qualidade de vida, classe funcional e idade em portadores de marca-passo cardíaco

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Abstract

Objective: To evaluate whether there is a correlation between quality of life and functional class in early heart pacemaker in patients, and its relationship with age.

Methods: 107 patients of both sexes (49.5% female /50.5% male) were investigated, average implant time of 6.36 months (± 2.99), and average age of 69.3 years (± 12.6). To assess the FC, a scale suggested by Goldman was used; for QoL the SQUAREL questionnaire was used, associated with SF-36. Statistical analysis was conducted using Spearman's correlation with 5% significance.

Results: Negative correlations were observed between QoL and FC: SQUAREL in the three domains, chest discomfort ($r=-0.197$, $P=0.042$), dyspnea ($r=-0.508$, $P=0.000$), arrhythmia ($r=-0.271$, $P=0.005$), and the SF-36 in the eight domains. Regarding age, there was a negative correlation with the SF-36 Functional Capacity ($r=-0.338$, $P=0.000$) and no correlation was found with SQUAREL. Positive correlation ($r=0.237$, $P=0.014$) was observed between age and FC.

Conclusion: In this study we found a significant negative correlation between QoL and FC, indicating that patients in this sample who belong to a better FC demonstrated better QoL. The older the patient, QoL is worse in functional capacity and FC. It is suggested that age and FC influence QoL, and the functional classification scales may be established as one of the assessment tools and reflect QoL in patients with pacemakers.

Descriptors: Quality of life. Pacemaker, artificial. Indicators of quality of life.

Resumo

Objetivo: Avaliar se existe correlação entre qualidade de vida e classe funcional em pacientes no pós-implante de marca-passo cardíaco, e sua relação com idade.

Métodos: Investigados 107 pacientes de ambos os sexos (49,5% do sexo feminino e 50,5% do sexo masculino), tempo

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Abbreviations, Acronyms & Symbols

FC	functional class
QOL	quality of life
ICD	implantable cardioverter defibrillator

médio de implante $6,36 \pm 2,99$ meses e média de idade $69,3 \pm 12,6$ anos. Para avaliação da classe funcional, foi utilizada escala proposta por Goldman e para qualidade de vida, questionário AQUAREL associado ao SF-36. Realizada análise estatística pela correlação de Spearman, com significância de 5%.

Resultados: Foram observadas correlações negativas entre qualidade de vida e classe funcional: AQUAREL nos três domínios, desconforto no peito ($r=-0,197$, $P=0,042$), dispneia ($r=-0,508$, $P=0,000$), arritmia ($r=-0,271$, $P=0,005$) e, no SF-36

nos oito domínios. Em relação à idade, correlação negativa com Capacidade Funcional do SF-36 ($r=-0,338$, $P=0,000$) e não se observou correlação com AQUAREL. Entre idade e classe funcional observou-se correlação positiva ($r=0,237$, $P=0,014$).

Conclusão: Neste estudo, encontrou-se correlação negativa entre qualidade de vida e classe funcional, evidenciando nesta amostra que os pacientes pertencentes a melhor classe funcional apresentaram melhor qualidade de vida. Conforme maior idade, pior a qualidade de vida em Capacidade Funcional e em classe funcional. Sugere-se, que idade e classe funcional influenciam qualidade de vida e as escalas de classificação funcional podem constituir um dos instrumentos que integram a avaliação e refletem a qualidade de vida em portadores de marca-passo.

Descritores: Qualidade de vida. Marca-passo artificial. Indicadores de qualidade de vida.

INTRODUCTION

The complex cardiac stimulant is released by a process of cell specialization and reflects the effort of millions of years in the phylogeny for the maintenance of life. Naturally, the replacement of components of the conduction system, with the maintenance of their properties, has always been a major challenge in the field of cardiac electrotherapy [1].

The normal process of conducting the heart is damaged when one of the coronary vessels is obstructed, making the conduction blocked. When this type of abnormality is detected, it can indicate pacemakers implantation, which consists of mechanisms of cardiac pacing, in order to correct or lessen the changes [2]. These electrical devices are responsible for providing cardiac electrical activity as physiological as possible, contributing primarily to correct heart rate and resynchronization of cardiac chambers [1,3].

Currently, artificial electrical cardiac pacing is no longer just a way to save patients' lives with atrioventricular blocks, becoming a way to correct heart rhythm disturbances and atrioventricular synchrony [4]. The concern went beyond prolonging life, but also enabling those patients achieve quality of life consistent with the average population. In this regard, several studies have been developed focusing on the quality of life of patients with pacemakers [3,5 - 11].

The term quality of life has many definitions. According to the World Health Organization, quality of life is the "individual's perception of their position in life within the

cultural context and values that he lives as well as in relation to their goals, expectations, standards and concerns" [12].

The evaluation of quality of life and its measurement, initially aimed to complement the survival analyzes, adding to other clinical parameters. However, this evaluation has broadened its scope when it became part of the cost-effectiveness analyses [13]. The concern with the concept of "quality of life" comes to rescue broader aspects than symptom control, reduced mortality or increased life expectancy. The quality of life related to health refers to a subjective view of the patient about their health status, and may be contrasted with physiological assessments with clinical interpretations relating to the patient welfare and their functional capacity [13,14].

Several tools have been proposed to assess the quality of life in health, the most used questionnaires are the the generic and specific ones [3,14-16]. For patients with pacemakers, the literature recommends using a specific questionnaire related to general health issues contained in a generic questionnaire [5-8].

According to Cunha et al. [9], the quick development in recent decades of sophisticated devices and the increasing number of indications for implantation of pacemaker, draw attention to the use of new methods that assess the quality of life and daily activity level of these patients. They observed in their studies important aspects of correlation between two forms of evaluation: quality of life and functional classification.

Functional rating scales are often used during evaluations of patients with pacemakers in order to categorize the degree of cardiovascular dysfunction. Among them, the Goldman scale is the most important one [3,5,17].

The instruments to assess quality of life and functional classification are a complementary way to assess the patients' physical, emotional and functional aspects. However, it is still debatable the correlation between functional class and quality of life of definitive cardiac pacemaker users. This question is the basis of this study, therefore, it is necessary to deeply discuss the theme "functional capacity and quality of life in patients with pacemaker", as suggested in studies by Stofmeel et al. [18] Oliveira et al. [8] and Cunha et al. [9].

The aim of this study was to evaluate the correlation between quality of life and functional class in patients after implantation of cardiac pacemakers, and their relationship with age.

METHODS

We conducted a cross-sectional study, a type of descriptive and quantitative observational study in patients with pacemakers, at the Department of Cardiac Surgery and Pacemaker at Santa Casa de Misericórdia, Marília, São Paulo. Data collection occurred from August 2009 to June 2010.

The minimum sample size was estimated at $n=85$, taking into account a 5% significance level ($\alpha=0.05$), a 20% type II error ($\beta=0.20$) and magnitude of effect $|r|=0.30$ [19]. The study was approved by FAMEMA Research Ethics Committee, protocol: #n° 442/08, in accordance with the Declaration of Helsinki. Volunteers signed an informed consent form.

The study included individuals of both genders, between three and 12 months after pacemaker implantation for conduction system disease, with no coronary artery disease and also clinically stable over the age of 18. We excluded individuals under the age of 18, patients that did not understand the sequence of tests, and also those that showed restraint of speech, hearing and understanding and individuals who did not want to participate.

The volunteers were evaluated using a protocol that included personal data, questions regarding the cardiac pacemaker (time, reason, pacing mode), comorbidities, functional class and quality of life questionnaires.

The functional classes was assessed by specific activity scale functional classification proposed by Goldman et al. [17], applied as an interview by a single trained individual. This scale consists of simple questions about specific activities, and each one relates to metabolic expenditure. Patients answered questions with "YES" or "NO" according to the statement of functional classification for that scale

and have been divided into functional classes: I (able to perform all the activities questioned equivalent to metabolic consumption ≥ 7 mets) II (perform activities with metabolic consumption ≥ 5 mets), III (able to perform activities with metabolic consumption ≥ 2 mets) and IV (unable to perform activities that require consumption above 2 mets) [3,8,9,17].

While evaluating the quality of life, we used two questionnaires that should be applied together in patients with pacemakers: quality of life questionnaire specific for patients with pacemakers, the Assessment of Quality of Life and Reletad events - SQUAREL and generic questionnaire The Medical Study 36-item Short-Form Health Survey - SF-36, [3,8,9]. Both instruments were translated and adapted to Portuguese and are valid, reliable and reproducible in the Brazilian population [8,15].

The questionnaire SQUAREL consists of twenty questions divided into three domains: chest discomfort, arrhythmia and dyspnea during physical activities. [3,6-8]. Chest discomfort involves the questions: 1 to 6 (regarding chest pain) and questions 11 and 12 (relating to dyspnea at rest). Arrhythmia is mentioned in questions 13 to 17. Dyspnoea during exercise includes questions 7 to 10 (relating dyspnea during exercise) and 18 to 20, (referring to fatigue) [3].

Each part consists of particular items which have five categories of response, with values from 1 to 5. The individual scores obtained for each part of the questionnaire were added up and computed by the formula shown in the data analysis. The final scores can range from zero (all complaints) to 100 (no complaints), when the latter represents perfect quality of life [8].

The SF-36 is a multidimensional questionnaire consisting of 36 items grouped into eight domains: functional capacity, physical aspects, pain, health status, vitality, social aspects, emotional conditions and mental health. It presents a final score from 0 to 100, where 0 corresponds to the worst and 100 to the best health status [15].

Regarding the sum of the scores, each questionnaire could vary their final score of 0 to 100, thus, a cut-off value of 50 was set (average) to determine the good and the bad areas. The areas that scored less than 50 would be with the worst quality of life and those that scored 50 or more would be with good quality of life [20].

AQUAREL and SF-36 questionnaires were applied in the form of an interview by a single examiner trained and unaware of the results of functional class. The sum of the points was performed according to literature descriptions for each questionnaire [3,15].

Statistical Analysis

Data were summarized using tables, absolute frequency, percentage, mean, standard deviation, maximum and minimum value.

In order to calculate the scores of the three domains of the questionnaire to measure SQUAREL quality of life (chest discomfort: questions 1 to 6, 11 and 12; dyspnoea: questions 7-10, 18-20; arrhythmia: questions 13 to 17) (1) de Oliveira [3] (203, p.46) equation was used with the following letters equivalence for the responses of each question of SQUAREL questionnaire and a 5-point Likert scale: a) = 5 b) 4 = c) = 3, d) = 2) and e) = 1.

Equation = $100 - \{[(\Sigma N - n^{\circ} N) / (\text{number NX } 5) - n^{\circ} N]\} \times 100$. Where: ΣN = summation of scores of questions that compose the score and $n^{\circ} N$ = number of questions that compose the score.

In the study of correlations among quantitative variables, the non-parametric Spearman test (r_s) was used. The significance level adopted was 5% of probability to reject the null hypothesis.

RESULTS

We evaluated 107 individuals of both genders (49.5% female and 50.5% male) with a mean implant pacemaker period of 6.36 months (± 2.99 months), mean age of 69.3 years (± 12.6 years). We observed 12.1% of Chagas disease, 64.5% of hypertension, 24.3% of diabetes mellitus and 48.6% were non-smokers. In relation to functional class, the majority with 70% class I. Table 1 presents the sample characterization.

The study results showed significant negative correlations between quality of life and functional class. In the SQUAREL analysis, we observed a negative correlation between overall quality of life and in all three areas: chest discomfort, dyspnea and arrhythmia with functional class. On the other hand, we did not observe a correlation with quality of life regarding age by SQUAREL (Table 2).

There were also significant negative correlations between the SF-36 in all its domains and functional class. Regarding age, there was a significant negative correlation with physical functioning (Table 3).

In studying the association between age and functional class, there was a significant positive correlation ($r=0.237$, $P=0.014$).

DISCUSSION

Quality of life x functional classification

According to a recent publication of the Brazilian Pacemakers, Resynchronizers and Defibrillators Registry (RBM) in 2012, while analyzing the implants of cataloged pacemakers, the current profile of indications is: 11.4% of patients in class I, 15.9% in class II, 41.3% in class III and 31.3% in class IV [21]. These numbers represent the universe of cardiac pacing in Brazil, the indications are prevalent in patients in classes III and IV.

Table 1. General characteristics and clinical study in 107 patients.

Variables	%
Gender	
Female	49.5
Male	50.5
Education	
Illiterate	30.8
Incomplete Elementary School education	55.1
Incomplete High School education	1.9
High School	7.5
Higher Education	3.7
Chagas Disease	
Yes	12.1
No	87.8
Implant indication	
Atrioventricular block	57.9
Sinus node disease	28.0
Others	14.1
Types of stimulation	
Bicameral	86.9
Unicameral	13.1
Implantation time (months)	
Mean (SD)	6.36 \pm 2.99
Minimum – Maximum	1 - 13
Functional Classification	
Class I	70
Class II	7
Class III	21
Class IV	2

Table 2. Mean values of quality of life (AQUAREL), and correlations between the domains of the questionnaire with functional class and age.

	Chest pain	Dyspnea	Arrhythmia	Total AQUAREL
Mean (SD)	90.8 \pm 14.9	75.0 \pm 21.3	89.0 \pm 14.1	84.9 \pm 13.9
Correlation coefficient				
Functional class	$r=-0.197$ $P=0.042^*$	$r=-0.508$ $P=0.000^*$	$r=-0.271$ $P=0.005^*$	$r=-0.441$ $P=0.000^*$
Age	$r=0.188$ $P=0.052$	$r=-0.041$ $P=0.678$	$r=0.051$ $P=0.600$	$r=0.028$ $P=0.774$

* Significant ($P<0.05$). Spearman correlation test

Table 3. Mean values of quality of life (SF-36), and correlations between the domains of the questionnaire with functional class and age.

	Functional Capacity	Physical Aspects	Pain	Health Conditions	Vitality	Social Aspects	Emotional Aspects	Mental Health
Mean (dp)	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
Correlation coefficient								
Class	r=-0.686	r=-0.359	r=-0.356	r=-0.465	r=-0.462	r=-0.194	r=-0.336	r=-0.358
Functional	P=0.000*	P=0.000*	P=0.000*	P=0.000*	P=0.000*	P=0.045*	P=0.000*	P=0.000*
Age	r=-0.383	r= 0.063	r=-0.089	r=-0.089	r=-0.044	r=-0.070	r=-0.003	r=0.093
	P=0.000*	P=0.520	P=0.360	P=0.360	P=0.651	P=0.476	P=0.973	P=0.340

* Significant (P < 0.05). Spearman correlation test

Regarding the assessment of quality of life with AQUAREL and SF-36 questionnaires, it was observed that no domain resulted in values below 50, showing that the patient quality of life after implantation is above average, therefore, the quality of life for these patients was good.

Analyzing the highest and the lowest scores in AQUAREL, the lowest quality of life according to patients' opinion was in the dyspnea domain with 75 and, the best quality in discomfort with 90.8, the factor which was less affected in the life of these patients. In the SF-36 questionnaire, the domain with the highest quality of life was the social aspects with 89.1, it was also observed that the physical domain (impact of physical health on performance of daily activities and / or professional) had the lowest average in the both questionnaires with 58.4, but the most affected in patients' opinion.

These findings corroborate with the study by Oliveira [3], which evaluated the quality of life (AQUAREL and SF-36) in 139 patients with pacemakers and, observed impairment in quality of life by AQUAREL in dyspnea (75.3) and better quality in discomfort (85.3). In the SF-36, the worst quality of life was emotional (46.7), followed by physical (51.4) and best quality of life in social aspects (74.3).

Cesarino et al. [22] studied the quality of life in 50 patients with implantable cardioverter defibrillators (ICDs) by the SF-36. The social domain had the highest score (80.5) and the worst was the physical one (40.5), in agreement with this study.

We observed a negative correlation between all domains of quality of life and functional class in patients with pacemakers, suggesting that those individuals belonging to the best functional class had higher QOL scores, and those belonging to the worst levels of functional class (in this study, class III and IV) had the lowest scores. In accordance with the findings of Cunha et al. [9] who studied functional class in their research (Goldman) and

quality of life (AQUAREL and SF-36) in 14 patients with pacemakers, also observed a significant correlation among the instruments: in the three domains of AQUAREL with functional class; and the SF-36 questionnaire, vitality, pain and functional capacity with functional class.

In the study of Stofmeel et al. [6,7], with 74 patients with pacemaker, a negative correlation of scores of quality of life (AQUAREL and SF-36) was observed with the functional classification of New York Heart Association (NYHA).

According to Oliveira et al. [8], the observed correlations among AQUAREL scores and instruments already recognized, such as the SF-36 scale and functional classification of Goldman, suggest that AQUAREL is an instrument for assessing quality of life capable of registering through its variation of their specific scores, changes in subjective points of view of patients with pacemakers. In accordance with this study, we also observed correlations between functional class and quality of life.

Oliveira et al. [23] studied quality of life in 139 patients with pacemakers, identified relationship between poorer quality of life related to health in patients with pacemakers with Chagas disease, female gender, unmarried status and the worst functional class. In multivariate analysis, the worst functional class stood out as an independent predictor of poor quality of life related to health in the physical component of the SF-36 and in all domains of AQUAREL.

Therefore, this study also showed a direct relationship of functional class, which reflects the degree of heart failure, quality of life in patients with pacemakers, confirming reports by other authors, such as Stofmeel et al. [18] Oliveira et al. [8,23]; Cunha et al. [9].

Age x quality of life x functional classification

According to Cunha et al. [9], the literature contains conflicting results regarding the correlation between age and quality of life in different populations [14,24,25]. It is believed that age has a relationship mainly with variables

relating to patients' physical condition [9,24,26].

In this study, we observed a negative correlation between age and the physical functioning domain of SF-36, one of which represents the physical condition. This domain indicates how much health conditions interfere with everyday activities, suggesting that patients with advancing age have greater impairment in physical and functional activities, thus with worse quality of life in functional capacity. Similar to these findings, Cunha et al. [9] observed a negative correlation between age and the SF-36 in the physical functioning domain, on the other hand, we also found a correlation between age and emotional aspect, supporting the controversial issue of the relationship between quality of life and age.

Van Eck et al. [27] studied quality of life in patients awaiting pacemaker implantation with a control population (without pacemakers). They emphasized that the most important predictors of a good quality of life were age, presence of cardiac comorbidities and atrial fibrillation. They also reported that age is inversely related to the quality of life, in accordance with the findings of this study.

In agreement with the results of Cunha et al. [9] the present study did not find any correlation between quality of life by AQUAREL and age. The authors explained in their paper that possibly this difference of association between age and the two instruments of quality of life is due to the fact that SF-36 is a generic questionnaire and has broader domains, which may cover different aspects susceptible to interference of age.

However, Cesarino et al. [22], research on perception of quality of life (SF-36) in patients with IDC, observed that the quality of life in relation to age showed no statistically significant difference. Two studies developed in the state of Goiás also observed no significant association between the scores of quality of life and age: Gomes et al. [25] evaluated the quality of life (SF-36 and AQUAREL) after pacemaker implantation in 23 patients and Anthony et al. [11] evaluated the quality of life (SF-36) of 25 cardiac patients eligible for implantation of pacemaker in a hospital.

The age reflects the aging, which is a non-modifiable risk factor, with greater frequency and greater severity in cardiovascular disease. Even though the pacemaker implantation may provide a benefit in terms of quality of life, this is not often measured in older populations due to other coexisting diseases and lower life expectancy [25].

In the present study we observed significant positive correlation between age and functional class, suggesting that older patients had worse functional class. We believe that this fact can be explained by the physiology of aging, because the scale of Goldman is sensitive to detect reduction of activities that relate to the ability to perform tasks that require a certain metabolic expenditure, disagreeing with the results of Cunha et al. [9] since no correlation was found.

It is suggested that the functional classification scales may constitute one of the tools that integrated the assessment and reflect the quality of life in patients with pacemakers, may help health staff in clinical practice.

CONCLUSION

In this study, negative correlation was found between all domains of quality of life with functional class. Age was negatively correlated with quality of life and functional class.

The age and functional class have influence on quality of life, so these variables must be considered in strategies to improve quality of life in individuals with pacemakers.

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