

## CORRELATION BETWEEN FUNCTIONAL CLASS AND QUALITY OF LIFE AMONG CARDIAC PACEMAKER USERS

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### ABSTRACT

**Introduction:** Growing technological progress in treating patients with heart conduction disturbances has provided such patients with better life conditions. Functional classification (FC) scales and quality of life (QOL) questionnaires are additional means for evaluating patients' physical, emotional and functional characteristics. However, the question remains as to whether there is any association between FC and perception of QOL among pacemaker users. **Objective:** To evaluate whether there is any correlation between FC and QOL among definitive cardiac pacemaker users. **Method:** Fourteen pacemaker users were evaluated. To assess FC, the specific activity scale proposed by Goldman was used. To evaluate QOL, the Aquarel questionnaire was used in association with SF-36. The Spearman correlation test was applied to investigate whether there was any association between the variables, considering  $p < 0.05$  to be significant. The SPSS for Windows software, version 10.0, was used for the data analysis. **Results:** There was a significant negative correlation between FC and QOL through evaluation by Aquarel questionnaire in its three domains: chest discomfort ( $r = -0.666$ ;  $p = 0.009$ ); dyspnea ( $r = -0.604$ ;  $p = 0.022$ ); and arrhythmia ( $r = -0.550$ ;  $p = 0.041$ ). Among the eight domains of SF-36, three showed a significant correlation with FC: physical functioning ( $r = -0.745$ ;  $p = 0.002$ ); pain ( $r = -0.667$ ;  $p = 0.009$ ); and vitality ( $r = -0.591$ ;  $p = 0.026$ ). **Conclusion:** In the present study, a significant correlation was found between FC and QOL, thus suggesting that functional classification scales may reflect aspects of QOL among pacemaker users.

**Key words:** pacemaker; functional class; quality of life.

### RESUMO

#### Correlação Entre Classe Funcional e Qualidade de Vida em Usuários de Marcapasso Cardíaco

**Introdução:** Os crescentes avanços tecnológicos desenvolvidos para o tratamento de distúrbios de condução cardíaca vêm proporcionando aos pacientes melhores condições de vida. As escalas de classificação funcional e questionários de qualidade de vida (QV) constituem uma forma suplementar de avaliação dos aspectos físicos, emocionais e funcionais dos pacientes. Entretanto, permanece a seguinte questão: existe correlação entre a classe funcional (CF) e a percepção da QV em usuários de marcapasso (MP)? **Objetivo:** O objetivo do estudo foi avaliar se existe correlação entre classe funcional (CF) e QV em portadores de MP cardíaco definitivo. **Métodos:** Foram avaliados 14 usuários de MP. Para avaliar CF, foi utilizada a escala de atividade específica proposta por Goldman, e, com objetivo de avaliação da QV, foi aplicado o questionário Aquarel associado ao SF-36. Com o objetivo de verificar se existe correlação entre as variáveis, foi aplicado o teste de correlação de Spearman, considerando como significativo  $\alpha < 0,05$ . Para a análise dos dados, foi utilizado *Software SPSS for Windows* versão 10.0. **Resultados:** A CF correlacionou-se inversa e significativamente com a QV avaliada pelo Aquarel em seus três domínios: desconforto no peito ( $r = -0,666$ ;  $p = 0,009$ ); dispnéia ( $r = -0,604$ ;  $p = 0,022$ ) e arritmia ( $r = -0,550$ ;  $p = 0,041$ ). Já em relação ao SF-36, dos seus oito domínios, três estabeleceram uma correlação significativa com a CF: capacidade funcional ( $r = -0,745$ ;  $p = 0,002$ ); dor ( $r = -0,667$ ;  $p = 0,009$ ) e vitalidade ( $r = -0,591$ ;  $p = 0,026$ ). **Conclusão:** No presente estudo, encontrou-se correlação significativa entre CF e QV, sugerindo que as escalas de classificação funcional podem refletir aspectos da QV de portadores de MP.

**Palavras-chave:** marcapasso; classe funcional; qualidade de vida.

## INTRODUCTION

Permanent cardiac pacemaker (PM) therapy was initially introduced to provide life-saving conditions to patients through the use of fixed frequency equipment, which frequently competed with the patient's heart rate. Technological advancements and the advent of rate-responsive PMs, which adapt to the patient's individual needs, allowed hemodynamic improvement, greater exercise capacity and better quality of life (QoL)<sup>1,2</sup>. In this context, it is very important to evaluate and learn about the various instruments which can be used to assess the impact of the therapy employed. The functional classification scales are frequently utilized during the evaluation of this patient population in order to determine the degree of cardiovascular dysfunction. Among them, the specific activity scale proposed by Goldman<sup>3</sup> stands out. It is based on metabolic costs and the appearance of symptoms during the assessment of specific activities of daily life<sup>4-6</sup>. The QoL questionnaires also constitute an additional approach to clinical practice<sup>6</sup>. These instruments reflect the patient's perceived health, covering functional, psychological, cognitive and social aspects<sup>6,7</sup>. The literature includes generic and specific instruments used during the assessment of QoL<sup>6,8-10</sup>. The Assessment of Quality of Life and Related Events (Aquarel) is a specific questionnaire for pacemaker users which has to be used with the generic Medical Outcomes Study 36 – Item Short Form Health Survey (SF-36)<sup>6,7,10,11</sup>. Several studies use these measurements to assess PM users<sup>12</sup> and different populations such as heart failure sufferers<sup>13</sup>. It is assumed that there is a link between QoL and functional classification scales. However, few studies until now have investigated the relationship between these variables. In light of that, the objective of this study was to determine whether there is a correlation between functional class (FC), assessed through the specific activity scale proposed by Goldman, and QoL, measured by the Aquarel questionnaire associated with SF-36 in permanent PM users.

## METHODOLOGY

The size of the sample was calculated based on the results of a pilot-study considering power test equal to 80% and  $\alpha = 0.05$ , which indicated the need to assess 13 volunteers. The study had been previously approved by the Ethics and Research Committee of Universidade Federal de Minas Gerais (n° 219/01). In addition to that, the volunteers signed a free and informed consent before the beginning of the assessments.

The study included male and female individuals aged 18 to 65 who had an implanted PM for more than three months and were clinically stable. Individuals were

excluded if they were older than 65, had less than five years of schooling and had problems with locomotion and associated pathologies (respiratory, orthopedic or neurological). Initially, the selected individuals were informed of the objective and outline of the study, and an interviewer completed a clinical form with their personal details, time period and reasons for the PM implant, form of stimulation, use of medication and associated pathologies.

A previously trained assessor interviewed the volunteers to determine the FC using the functional classification form for the specific activity scale proposed by Goldman. This form consists of a series of yes/no questions. Its validity and reproducibility are well established in the literature, and it functionally classifies individuals based on the metabolic costs and the appearance of symptoms during the performance of activities of daily life<sup>3</sup>.

To assess QoL, individuals filled in the Aquarel questionnaire designed specifically for PM users and to be used with the SF-36, a generic instrument widely used in this field. Both instruments were translated into Brazilian-Portuguese, and the instruments validity, reliability and reproducibility are well established in the Brazilian population<sup>11</sup>. Aquarel consists of 20 questions and three domains: chest discomfort, arrhythmia, dyspnea, while the SF-36 consists of eight domains: physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role-emotional and mental health<sup>6,7,11</sup>. The questionnaires were applied in interview form by the same previously trained assessor blinded to the FC results.

First, descriptive statistics were used to characterize the sample. The Spearman correlation coefficients were used to determine the associations between the variables.

The statistical significance of the data was set at 5% ( $\alpha < 0.05$ ). The Statistical Package for the Social Sciences (SPSS) 10.0 for Windows was used for the data analysis.

## RESULTS

Fourteen volunteers were assessed. Table 1 presents the characteristics for the sample. The reasons for the PM implant were as follows: Chagas' disease, atrioventricular block, sinus node disease and congenital cardiopathies.

The results of the study showed significant negative correlations between FC and QoL. The analysis of the Aquarel questionnaire showed a negative correlation between FC and QoL in its three domains: chest discomfort ( $r = -0.666$ ;  $p = 0.009$ ); dyspnea ( $r = -0.604$ ;  $p = 0.022$ ) and arrhythmia ( $r = -0.550$ ;  $p = 0.041$ ) (Table 2). In regard to SF-36, of the eight domains, three had significant correlations with FC: physical functioning ( $r = -0.745$ ;  $p = 0.002$ ); bodily pain ( $r = -0.667$ ;  $p = 0.009$ ) and vitality ( $r = -0.591$ ;  $p = 0.026$ ). This data is demonstrated in Table 3.

**Table 1.** Sample characterization.

Characteristics	
Gender	8 F/6 M
Age (years)	42.85 ± 13.75 *
Time period of implant (years)	4.6 ± 2.4 *
Education (years)	6 ± 1.3 *
Stimulation methods	2 single-chamber/ 12 dual-chamber
<b>Functional classification</b>	
I	7
II	2
III	5

\* Mean ± standard deviation; F= females; M= males.

In contrast, the analysis of the Aquarel questionnaire found no significant correlation between age and QoL (Table 2). Nevertheless, the SF-36 showed a negative correlation between age and QoL in the role-emotional domain ( $r = -0.624$ ,  $p = 0.017$ ) and the physical functioning domain ( $r = -0.669$ ,  $p = 0.009$ ) (Table 3).

With regard to the relationship between age and FC, there were no significant values ( $r = 0.468$ ,  $p = 0.092$ ).

**Table 2.** Correlation between functional class, age and quality of life assessed with Aquarel.

	Chest discomfort	Dyspnea	Arrhythmia
<i>Functional Class</i>	$r = -0.666$	$r = -0.604$	$r = -0.550$
	$p = 0.009^*$	$p = 0.022^*$	$p = 0.041^*$
<i>Age</i>	$r = -0.292$	$r = -0.119$	$r = -0.436$
	$p = 0.311$	$p = 0.685$	$p = 0.119$

\* $p < 0.05$ .

**Table 3.** Correlation between functional class, age and quality of life assessed with SF-36.

	Social Functioning	Vitality	Bodily Pain	General Health	Role-Physical	Mental Health	Role-Emotional	Physical Functioning
<i>Functional Class</i>	$r = -0.450$ $p = 0.106$	$r = -0.591$ $p = 0.026^*$	$r = -0.667$ $p = 0.009^*$	$r = -0.439$ $p = 0.116$	$r = -0.149$ $p = 0.612$	$r = -0.384$ $p = 0.175$	$r = -0.186$ $p = 0.525$	$r = -0.745$ $p = 0.002^*$
<i>Age</i>	$r = -0.482$ $p = 0.081$	$r = -0.07$ $p = 0.793$	$r = -0.453$ $p = 0.104$	$r = -0.228$ $p = 0.433$	$r = 0.073$ $p = 0.804$	$r = -0.269$ $p = 0.353$	$r = -0.624$ $p = 0.017^*$	$r = -0.669$ $p = 0.009^*$

\* $p < 0.05$ .

## DISCUSSION

In the last few decades, the rapid development of sophisticated devices and the increase in MP implant recommendations draw attention to the use of instruments that assess individuals' perceived health and the level of activities of daily life. This study found important aspects of relationship between two of these assessment methods: quality of life (QoL) and functional classification (FC), which will be specifically discussed below.

### Quality of life x functional classification

A significant negative correlation was found between functional classification, proposed by Goldman, and QoL in patients with MP. This suggests that those individuals who presented better FC had higher QoL scores, while the ones who presented the worst levels of FC (in the present study, class III) had the lowest scores. This result was more evident after analysis of the Aquarel questionnaire, a specific instrument used to assess QoL in MP users.

Oliveira<sup>11</sup> found similar results. He studied a similar population of PM patients, using the specific activity scale proposed by Goldman as a reference guide in the attempt to validate Aquarel (within the Brazilian population), and found a significant correlation between those instruments.

Stofmeel et al.<sup>10</sup>, in a review of the importance of QoL for MP users, described the development of Aquarel and praised its validity, reliability and good correlation

with functional classification. They also described it as a very important instrument which should be added to the traditional methods of assessment and diagnosis.

Specifically, there was a significant relationship between the three Aquarel domains and FC. However, when SF-36 was analyzed, only three domains demonstrated significant correlation: vitality, bodily pain and physical functioning. The detailed analysis of these three domains can explain the results. Vitality assesses the energy and eagerness displayed by the volunteer. Bodily pain classifies the occurrence and intensity of pain symptoms as well as their interference in the individual's daily life. Finally, physical functioning indicates how much the individual's health condition interferes in activities of daily life<sup>13</sup>. Therefore, the fact that the abovementioned SF-36 domains have a direct relationship with possible limitations to activities of daily life may have determined a greater association of these variables with functional classification.

### Age x quality of life

The literature presents controversial results regarding the correlation between age and quality of life in different populations<sup>14</sup>. In this context, the detailed analysis of SF-36 presents important characteristics. SF-36 allows the combination of the eight assessed domains into two different categories: physical and mental condition. The physical condition would be determined by the following domains: physical functioning, role-physical, bodily pain and general health. The mental condition would consist of mental health, role-emotional, social functioning and vitality. It is believed that age correlates mainly with the variables related to physical condition<sup>14</sup>.

The findings of the present study are in accordance with this claim given the significant negative correlation observed between age and SF-36 in the function capacity domain (one of the main determinants of physical condition). In contrast, an association between age and role-emotional has been found, which illustrates this controversy.

The non-association between age and the Aquarel data is another important aspect which has been observed. The difference in association between the two QoL instruments may be due to the fact that SF-36 is a generic questionnaire with broader domains capable of encompassing different aspects susceptible to the interference of age.

### Age x functional classification

Regarding the association between age and FC, no significant values were found. This can be due to the fact that the functional classification scales presented a relationship with the volunteers' symptoms and not with their age.

### Limitations of the study

With regard to age, time period of the implant and basic pathologies, the diversity of the sample may have been a source

of confusion. And although the sample calculation indicated that the number of individuals was sufficient to answer the question of the study, the low number of participants did not allow additional stratification analyses of the sample.

## CONCLUSION

The present study found a significant correlation between FC and QoL, assessed by Aquarel in its three domains: chest discomfort, dyspnea and arrhythmia. The SF-36 assessment also yielded significant results, but only in three of the eight domains: physical functioning, bodily pain and vitality.

Thus it can be inferred that the functional classification scales may reflect the QoL of PM users. This in turn could help health professionals during therapeutic intervention.

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