Health Related Quality of Life in Patients with Refractory Chronic Heart Failure Undergoing Cardiac Resynchronization: Type of Therapeutic Response

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Abstract

The benefits of cardiac resynchronization therapy (CRT) in the health-related quality of life (HRQL) are largely demonstrated in selected patients with severe congestive heart failure (CHF). However, the differences between responders and non-responders, with regard to the effect of CRT in the various dimensions that constitute HRQL are still a matter of discussion. *Objective:* To evaluate the impact of CRT on the HRQL of patients with CHF refractory to optimal pharmacological therapy, within 6 months after CRT. *Methods:* 43 patients, submitted to successful implantation of CRT, were evaluated in hospital just before intervention and in the outpatient clinic within 6 months after CRT. HRQL was analyzed based on the Kansas City Cardiomyopathy Questionnaire (KCCQ). Patients were classified as super-responders (ejection fraction of left ventricle - LVEF - ≥45% post-CRT), n=15, responders (sustained improvement in functional class and LVEF increased by 15%), n=19, and non-responders (no clinical or LVEF improvement), n=9. *Results:* In the group of super-responders, CRT was associated with an improvement in HRQL for the various fields and sums assessed ($\rho<0.05$); in responders, CRT has been associated with an improvement of HRQL in the various fields and sums, except in the self-efficacy dimension ($\rho<0.05$); in non-responders, CRT was not associated with improvement of HRQL. *Conclusion:* In a population with severe CHF undergoing CRT, the patients with clinical and echocardiographic positive response, obtained a favorable impact in all dimensions of HRQL, while the group without response to CRT showed no improvement. These data reinforces the importance of HRQL as a multidimensional tool for assessment of benefits in clinical practice.

Key words

Introduction
Congestive heart failure (CHF) is a progressive syndrome with a high incidence and prevalence and poor prognosis: four-year mortality is around 50% (1). With ageing populations, increased survival following acute coronary syndrome and prevention of sudden arrhythmic death, many patients will develop dilated cardiomyopathy, which, because of its symptoms, patients' awareness of their risk of dying, and the effects of therapy, together with frequent hospitalizations, has considerable impact on patients' health-related quality of life (HRQL).

The widespread use of HRQL instruments in research into CHF (both generic and specific) reflects the growing importance of this measure in clinical practice. Various studies have demonstrated its high prognostic value in predicting hospital readmission and mortality, and it is widely used as a predictor of outcomes of intervention in CHF patients (2-5).

Assessment of patients' state of health in clinical terms, or HRQL, is multifactorial, self-administered, subjective, and varies over time(6). This subjectivity refers to the fact that HRQL can only be told by the one who is measured and not to the psychometrics proprieties of the instrument that must be valid and reliable.

The benefits of cardiac resynchronization therapy (CRT) in the HRQL have been largely demonstrated in selected patients with severe CHF. However, the differences between responders and non-responders, with regard to the effect of CRT in the various dimensions of HRQL is still a matter of discussion.

The aim of this study was to evaluate the impact of CRT on the HRQL of patients with CHF refractory to optimal pharmacological therapy regarding the type of therapeutic response, within 6 months after CRT.

Methods

Population

43 patients, submitted to successful implantation of CRT were classified as super-responders (left ventricle ejection fraction - LVEF - ≥45% post-CRT), n=15, responders (sustained improvement in functional class and LVEF increase by 15%), n=19 and non-responders (no clinical or LVEF improvement), n=9 (Table 1).

Table 1 – General Population Characteristics

	Type	Superesponders (n=15)	Responders (n=19)	Nonresponders (n=9)
Age	M	65,1	63,2	62,8
	DP	8,2	11,1	6,0
Gender	Male	46,7%	84,2%	77,8%
	Female	53,3%	15,8%	22,2%
LVEF pré-CRT	M	29,5%	22,6%	23,9%
	DP	4,5	6,2	6,5
NYHA	Class II			22,2%
	Class III	100%	100%	66,7%
	Class IV			11,1%

Material
HRQL was analyzed based on a specific measure for the CHF, the Kansas City Cardiomyopathy Questionnaire (KCCQ) validated to Portugal (7). This instrument is composed of 23 itens divided into 5 domains: physical limitation, symptoms, quality of life, self-efficacy and social interference. The physical limitation domain measures the extent to which CHF symptoms have resullimited some of the patient's physical activities over the previous two weeks. The symptom domain assesses the number of times that CHF symptoms such as fatigue, dyspnea or limb edema have occurred in the previous two weeks and whether there have been changes in symptoms during the same period. The self-efficacy domain measures the patient's knowledge of how to avoid worsening of symptoms and of what to do if this occurs. The quality of life domain evaluates patients' perception of their enjoyment of life and of their sense of discouragement due to their heart failure, while the social interference domain assesses how CHF affects the patient's lifestyle. To facilitate interpretability, two summary scores were developed: the first, the functional status score, combines the physical limitation and symptom domains, and the second, the clinical summary score, combines the functional status score with the quality of life and social limitation domains. Subjects are requested to answer the 15 questions using Likert scales (8).

Procedure
Patients were evaluated at the hospital just before CRT implantation and in the outpatient clinic within 6 months after CRT.

Results
In the group of super-responders, CRT was associated with a significant improvement in HRQL for all fields and sums assessed (Table 2).

Table 2 – Superesponders Health Related Quality of Life (n=15)

KCCQ Domains	Inicial Average (**M**)	6 months Average (**M**)	t-value (**t**)	p-value (**p**)
Physical Limitation	51,8	90,4	-6,5	0,000
Symptoms	53,9	84,5	-4,4	0,001
Self-efficacy	76,2	95,7	-2,4	0,035
Quality of Life	38,7	85,1	-5,0	0,000
Social Interference	55,8	85,7	-3,8	0,002
Funcional Status	55,3	87,7	-6,0	0,000
Clinical Summary	52,6	86,2	-6,1	0,000

In responders, CRT was associated with an improvement of HRQL in various fields and sums, except in the self-efficacy domain (Table 3).

Table 3 – Responders Health Related Quality of Life (n=19)

KCCQ Domains	Inicial Average (**M**)	6 months Average (**M**)	t-value (**t**)	p-value (**p**)
Physical Limitation	63,1	89,1	-5,7	0,000
Symptons	60,0	82,4	-3,6	0,002
Self-efficacy	76,9	83,3	-0,7	NS
Quality of Life	39,8	75,0	-5,3	0,000
Social Interference	63,9	90,2	-3,9	0,001
Funcional Status	62,6	86,6	-4,8	0,000
Clinical Summary	59,2	84,9	-5,0	0,000

N.S.- non significant

In non-responders, CRT was not associated with improvement of HRQL (Table 4).

Table 4 – Nonresponders Health Related Quality of Life (n=9)

KCCQ Domains	Inicial Average (**M**)	6 months Average (**M**)	t-value (**t**)	p-value (**p**)
Physical Limitation	25,2	59,1	-1,9	NS
Symptoms	46,5	63,6	-1,1	NS
Self-efficacy	95,8	97,5	-0,8	NS
Quality of Life	20,8	52,1	-1,6	NS
Social Interference	37,5	63,8	-1,3	NS
Funcional Status	38,0	63,8	-1,6	NS
Clinical Summary	34,8	60,1	-1,5	NS

N.S.- non significant

Discussion

The benefits of CRT in the HRQL have been largely demonstrated in selected patients with severe CHF, but the differences between responders and non-responders, with regard to the effect of CRT in the various dimensions of HRQL is still a matter of discussion.

This study clarifies the relation between the clinical and the patient evaluation of the CRT. There was no difference between these evaluations, with the responders indicating a better HRQL and the nonresponders identifying no changes in life.

About the responders, and because we use the KCCQ to measure HRQL in CHF, that is the only one who measures the self-efficacy, we have seen that what differentiates the superesponders from the responders is the self-efficacy domain, being the knowledge of the clinical condition improved on the superesponders during the follow-up.

In conclusion, in a population with severe CHF undergoing CRT, the patients with positive clinical response and reverse remodeling, obtained a favorable impact in all

dimensions of HRQL, while the group without response to CRT showed no improvement. These data reinforces the importance of HRQL as a multidimensional tool for assessment of benefits in clinical practice.

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