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Original Article

Short Term Predictors of Success after Cardiac Resynchronization Therapy.

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ABSTRACT

Background: In patients with symptomatic Heart Failure (HF) and wide QRS duration, cardiac resynchronization therapy (CRT) causes reduction of morbidity and mortality. However, it's unclear which patient features predict short-term response to this device therapy. The research aimed to study which cases characteristics could expect short-term clinical and echocardiographic response to CRT.

Methods: This prospective cohort study involved 40 patients indicated for CRT device. The study was conducted in the cardiology departments, faculty of medicine, Zagazig University, and Police hospital at the period from October 2018 to October 2020. Clinical, laboratory, electrocardiographic, and echocardiographic assessments were performed pre and six months after implantation.

Results: Forty patients undergoing CRT implantation were included among which, 30 (75%) patients were considered responders after six months. From the present study, the responders to CRT were more frequently to be females with younger age than non -responders. Non-ischemic HF, left bundle branch block (LBBB) morphology and New York Heart Association (NYHA) functional class III were significantly more frequent in responders. Furthermore, responders had significantly wider baseline QRS duration, smaller baseline LV diastolic and systolic dimension and volumes, greater ejection fraction, lower levels of brain natriuretic peptide (BNP), and more baseline intra-ventricular dyssynchrony.

Conclusions: We concluded that pre-implantation independent Predictors of good CRT response are LBBB morphology, septal to posterior wall mechanical delay, wide QRS duration, interventricular mechanical delay, NYHA functional class III, and lower levels of BNP. Large scale study is recommended for further verification of study results.

Keywords: NYHA; cardiac resynchronization; echocardiography; dyssynchrony index

INTRODUCTION

Patients with moderate or serious heart failure (HF) refractory to medical therapy, New York Heart Association (NYHA) class II, III, or IV, wide QRS duration, and extremely low left ventricular ejection fraction (LVEF) may benefit from cardiac resynchronization therapy (CRT) [1]. Clinical trials have shown that CRT decreases HF hospital-stay, and improves the quality of life (QoL) and cardiac functions, defined as left ventricular (LV) reverse re-modeling [2]. However, the number of cases that do not respond to this procedure ranges from 30 to 35%[3].

Different studies provide different clarification for how people react to CRT. The difference in LVEF or left ventricular end-systolic volume (LVESV) is usually used to assess echocardiographic response[3] Clinical response is measured by improvement in NYHA functional class[4] . However, some investigator explained the response to CRT in the form of a combination of several clinical measurements[4] or as a combination of both clinical and echocardiographic measurements[5].

Inter-ventricular or intra-ventricular conduction delay is associated with structural re-modeling in

HF, resulting in mechanical dyssynchrony and further HF worsening[6]. As structural re-modeling was reversed by CRT, it's possible that electric re-modeling would be reversed as well, given the positive clinical outcomes of HF patients who received CRT. There is little information on how the adverse electric changes affecting ventricular conduction and repolarization recover after CRT, and how this relates to clinical and echocardiographic outcomes[7]. Clinical trials have studied different variables that might predict response to CRT however, determination of the predictors to CRT response still remains challenge[8].

In the present study, we sought to determine predictors of short-term clinical and echocardiographic response to CRT.

METHODS

This prospective cohort study involved forty cases indicated for CRT device. Our study was conducted in the cardiology departments, faculty of medicine, Zagazig University, and Al Agouza Police hospital at the period of two years; from October 2018 to October 2020.

Written informed consent was obtained from all participants, the study was approved by the research ethical committee of Faculty of Medicine, Zagazig University and Al-Agouze Police hospital. The study was done according to The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving human.

Before the start of the study and in agreement with the local regulations followed, the protocols and all corresponding documents were stated for approval by Institutional Review Board (IRB) from Faculty of Medicine, Zagazig University.

Our study was prospective cohort comparative study in which cases before and six months after CRT device application were compared.

Subjects and Sample size: Forty cases represent the target population of this study; all cases were evaluated according to clinical status (NYHA classification), ECG (QRS duration), echocardiographic findings and brain natriuretic peptide (BNP) levels before and six months after device implantation. They are divided into to two groups: group 1 who are responders to cardiac resynchronization therapy and group 2 who are non-responders to cardiac resynchronization therapy.

The study enrolled adult cases aged > 20 years, NYHA functional class > II symptoms despite optimal medical therapy, sinus rhythm, LV ejection fraction (LVEF) ≤ 35% and QRS duration ≥ 120 ms.

We excluded cases with insufficient echocardiographic image quality, previous pacing by a pacemaker, atrial fibrillation, renal failure, current major hepatic disorder, surgery or major trauma, history of cerebrovascular stroke (CVS), recent infection or inflammatory conditions, malignancy and inability to give informed consent.

All cases were subjected to Personal history (name, age, sex, residence and occupation) and past history (hypertension, diabetes, ischemic heart disorder, history of previous medical illness, and history of previous drug intake). Full general examination (chest and abdominal examination) and clinical evaluation performed before CRT implantation and repeated at six months of follow–up.

Electrocardiogram (12-lead ECGs with a paper speed of 25 mm/s and a gain of 10 mm/mV) were performed before and and six months after CRT implantation. Standard transthoracic echocardiographic examinations with Doppler studies were performed at base-line and six months follow-up. M-mode from the parasternal images were used to measure LV end-diastolic and end-systolic dimensions and to measure septal to posterior wall motion delay (SPWMD) as a parameter of Intra-ventricular dyssynchrony[9]. Standard Doppler echocardiographic studies included the time between the onset of the QRS complex on the surface ECG and the onset of the left and right ventricle Pulsed Doppler waves were measured as the left and right ventricle pre-ejection intervals.

At the baseline and six months follow-up, tissue Doppler imaging and LV dyssynchrony assessments were completed using two- and four-chamber pictures, the sample volume was put in the LV basal and mid portions of the anterior, inferior, inferior septum, lateral, anterior septum, and posterior walls, and the time interval between the onset of the QRS complex and the maximum systolic velocity was measured for the 12 LV basal sections to assess the longitudinal movement of the LV to define LV desynchronization. The left ventricle systolic strain (global longitudinal strain) was assessed before and six months after CRT implantation using speckle tracking imaging.

CRT was administered via the subclavian or axillary veins. The LV lead was inserted into the posterolateral vein, which was chosen based on the anatomical characteristics of the veins, and then connected to the appropriate electrode[10].

Blood samples were obtained for analysis of BNP levels before and six months after CRT implantation to assess the response.

The response to CRT was assessed after six months by NYHA Class, QRS duration, echocardiographic findings and BNP Levels. Clinical responding was described as a change in NYHA class of >1 without requiring hospitalization for heart failure[9, 10]. An absolute increase in LVEF of >10% and/or a decrease in LV end systolic volume of >15 % were defined as echocardiographic responding [6, 7, 11, 12]. A decrease in QRS period of >20 ms was used to describe electrocardiographic responders[13]. Non responders were defined as an unchanging or worsening of the clinical, echocardiographic, any hospital-stay for unprovoked worsening heart failure or cardiac death due to worsening heart failure during the first six months after CRT[7]. In our study non responders did not fulfill the criteria of the responders.

STATISTICAL ANALYSIS

Data were collected in a master sheet, coded, entered and analyzed using both SPSS version 22 medical statistics software and Microsoft Excel v. 2019.Data were presented as Mean ± standard deviation for quantitative variables & number and percentage for qualitative variables. Data were coded, entered and analyzed by computer package (version 10). Categorical data were compared using chi-square and calculated. The significance level was considered at P-value <0.05 for chi-square and when confidence interval of odds ratio (CI of OR) not including 1 in its range. Recorded data were analyzed using the statistical package for social sciences, version 20.0 (SPSS Inc., Chicago, Illinois, USA).

RESULTS

The study population consisted of 26 (65%) males and 14 (35%) females, with a mean age of 59.78±10.25 years (range 35–76years old). At six months of follow-up, there was significant increase in the LVEF after pacing therapy (p < 0.001). Left ventricular volumes significantly decreased after CRT implantation (p < 0.001). LV end diastolic diameters and LV end systolic diameters significantly decreased (p < 0.001) (Table 1).

From our study, there were 30 (75%) responders and10 (25%) non responders of final outcome. Depending on the response to CRT, the responders were sub classified as 60.0% patients were clinical responders, showing improvement of NYHA functional class after CRT, 40.0% patients revealed electrical response after CRT, and 60.0%patients were classified as echocardiographic responders (Figure 1). Non responders were all the cases who did not get any type of responding (according to the definitions of responding to CRT).

Regarding to demographic data, the present study showed that the responders to CRT were more females (46.7% vs 0%; P 0.007) and younger age (57.8±10.9 vs 65.5±4.9; P 0.04) than non-responders. (Table 2).

Responders group had more patients with baseline NYHA class-III (86.7% vs 40%; P 0.01), more patients with non-ischemic cardiomyopathy (46.7% vs 0 %; P 0.007), more patients with LBBB (83.3% vs 30%; P <0.001), and lower levels of baseline BNP (518± 234 vs 723± 250; P 0.024) (table2).

Furthermore, echocardiographic parameters of mechanical dyssynchrony (IVMD, SPWMD, and systolic dyssynchrony by TDI) are important tools that can be used to help identify potential responders to CRT, the difference between the two groups regarding to mechanical dyssynchrony at the level of baseline assessment was statistically significant (p <0.05) (Table 2). Regarding to global longitudinal strain (GLS) by speckle tracking, responders had patients with more negative GLS (-6.7±1.8 vs -4±2.6: P 0.0.006). Furthermore, the improvement in GLS was more prominent in the responders as measured with delta GLS (5±2.6 vs 2.5±1.3; P 0.005). (Figure 2).

Univariate analysis revealed that significant predictors of good CRT response were LBBB Morphology, systolic dyssynchrony index >32ms, SPWMD, wide QRS duration, NYHA class III, younger Age (years), IVMD, BNP (lower levels), Etiology(DCM), and female gender. However, multivariate analysis did not find any significant predictors. Step wise forward conditional regression analysis demonstrated that LBBB Morphology, SPWMD, wide QRS Duration, IVMD, NYHA class III, and BNP were the best independent predictors of good CRT response with OR [7.055 (2.624-13.620) P=0.007, 5.216(2.376-14.159) P= 0.027, 3.111 (1.823- 5.304) P=0.029, 0.581 (0.235- 1.443) P=0.038; 5.216 (2.376- 14.159) P=0.027; and 2.236 (1.672- 2.991) P=0.043, and1.459 (1.351- 1.575) P=0.047] respectively (table 3).

Receiver operating characteristics (ROC) curve was performed for QRS duration and demonstrated an area under the curve of 0.817 (0.694-0.943) with P value 0.015. The best cut off value for prediction of good CRT response was ≥145 with sensitivity 70% and specificity 70%. while the best cut off value of EF% was ≥25, with sensitivity of 80% specificity of 66.7% and an area under the curve was 0.790 (0.672-0.901) with P value 0.026 (Figure 3).

Table (1): Comparison between baseline and after 6months according to echo parameters.

Echo parameters	Baseline	After six months	Mean Diff.	t-test	p-value
LVEDD (mm)					
Range	49 – 86	46 – 78	4.650	6.433	<0.001**
Mean±SD	67.78±7.01	63.13±7.96			
LVESD (mm)					

Echo parameters	Baseline	After six months	Mean Diff.	t-test	p-value
Range	13 – 77	30 – 68	6.350	6.035	<0.001**
Mean±SD	57.60±9.78	51.25±9.57			
LVEDV(ml)					
Range	100 – 410	76 – 375	27.150	5.848	<0.001**
Mean±SD	204.03±60.44	176.88±54.38			
LVESV(ml)					
Range	40 – 315	28 – 280	29.975	5.530	<0.001**
Mean±SD	148.40±32.26	118.43±37.66			
EF%					
Range	17 – 35	21 – 63	-7.850	-5.207	<0.001**
Mean±SD	27.05±4.59	34.90±11.62			

N= Number P= Probability of chance (significance), %= Percentage. Using: t-Independent Sample t-test; x^2: Chi-square test; Wilcoxon z-test; p-value <0.05 S. LVEDD: left ventricular end diastolic diameter, LVESD: left ventricular end systolic diameter, LVEDV: left ventricular end diastolic volume, LVESV: left ventricular end systolic volume, EF: ejection fraction, SD: standard deviation.

Table (2): Comparison between responder group and non -responder group according to demographic data, baseline NYHA class, Ventricular dyssynchrony and BNP levels.

			Responder (N=30)	Non responder (N=10)	Test	p-value
Demographic	Age (years)		57.87±10.90	65.50±4.93	4.53	0.040*
	Gender	Male	16 (53.3%	10 (100.0%)	7.179	0.007*
		Female	14 (46.7%	0 (0.0%)		
Etiology		ICM	16 (53.3%	10 (100.0%)	7.179	0.007*
		DCM	14 (46.7%	0 (0.0%)		
QRS morphology		RBBB	5 (16.7%	7 (70.0%)	10.159	<0.001**
		LBBB	25 (83.3%	3 (30.0%)		
NYHA class Base-line		Class-III (n=30)	26 (86.7%)	4 (40%)	x^2=6.400	0.011*
		Class-IV (n=10)	4 (13.3%)	6 (60%)		
Ventricular dyssynch	IVMD	Baseline	61.50±27.87	35.80±8.77	z=8.11	0.007*
		After 6months	31.20±12.01	30.80±8.28	z=0.01	0.923
	SPWMD	Baseline	116.40±40.10	75.50±19.64	t=9.51	0.004*
		After 6months	63.13±27.03	54.40±13.33	t=0.95	0.335
BNP		Baseline	518.53±234.77	723.80±250.92	5.55	0.024*
		After 6months	219.83±179.23	531.20±143.03	24.77	<0.001**

N= Number P= Probability of chance (significance), %= Percentage, Using: t-Independent Sample t-test; x^2: Chi-square test; Wilcoxon z-test; p-value <0.05 S. NYHA: New York Heart Association, IVMD: inter-ventricular mechanical delay, SPWMD: septal to posterior mechanical delay, BNP: brain natriuretic peptide.

Table 3: Univariate and Multivariate regression analysis to pick up predictors of good CRT response.

Parameters	Univariate analysis				Multivariate (Step wise forward conditional regression)			
	OR	Lower	Upper	p-value	OR	Lower	Upper	p-value
Age (years)	1.961	1.756	2.188	0.033*				
Sex (Female)	2.135	1.655	2.752	0.048*				
Etiology	1.643	1.565	1.725	0.042*				
IVMD	0.597	0.241	1.482	0.035*	0.581	0.235	1.443	0.038*

Parameters	Univariate analysis				Multivariate (Step wise forward conditional regression)			
	OR	Lower	Upper	p-value	OR	Lower	Upper	p-value
SPW MD	5.707	2.600	15.491	0.020*	5.216	2.376	14.159	0.027*
BNP	1.682	1.557	1.816	0.040*	1.459	1.351	1.575	0.047*
GLS	0.802	0.158	1.846	0.132				
QRS duration	3.194	1.872	5.446	0.027*	3.111	1.823	5.304	0.029*
LBBB Morphology	8.134	3.025	15.702	0.006*	7.055	2.624	13.620	0.007*
NYHA class III	2.446	1.829	3.272	0.031*	2.236	1.672	2.991	0.043*
SDI >32ms	7.570	4.002	21.260	0.010*				

OR= Odd Ratio, P= Probability of chance (significance), IVMD: inter-ventricular mechanical delay, SPWMD: septal to posterior mechanical delay, BNP: brain natriuretic peptide, GLS: global longitudinal strain, LBBB: left bundle branch block, NYHA: New York Heart Association: SDI: systolic dyssynchory index.

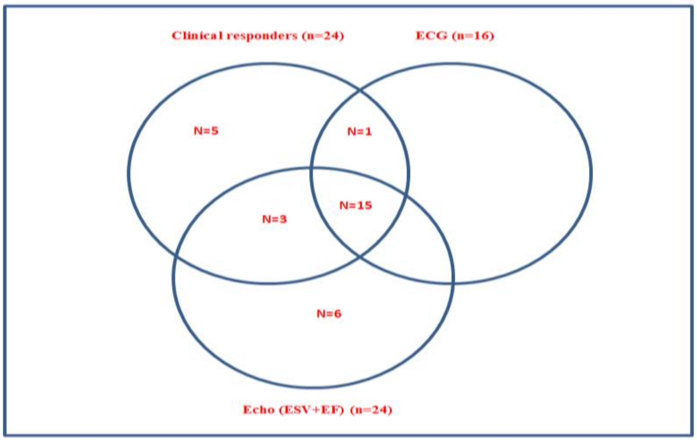

Fig. (1): Responders to CRT (24 patients were clinical responders; 16 patients were electrical responders and24 patients were echocardiographic responders).

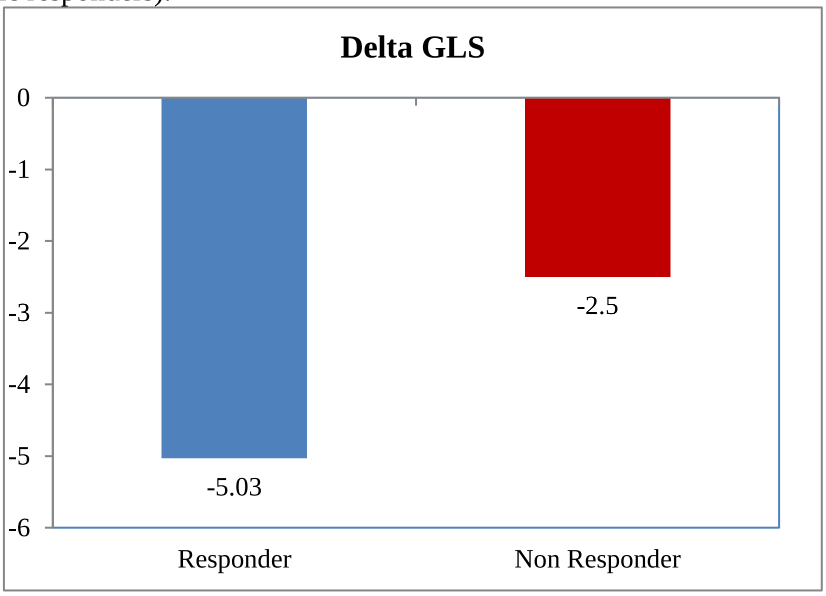

Fig. (2): Bar chart between responder group and non-responder group according to Delta GLS.

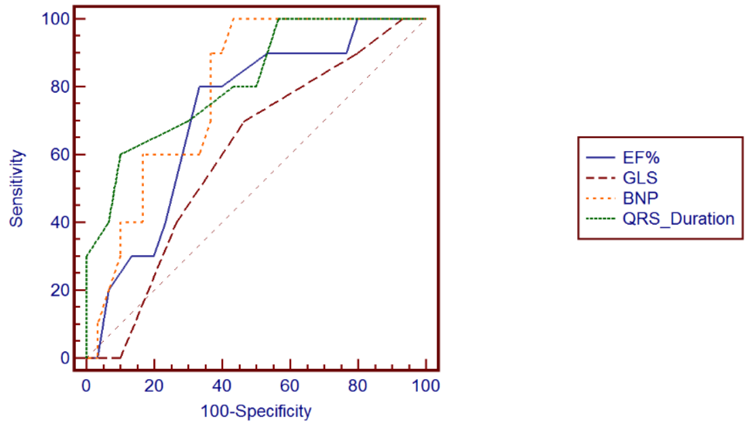

Fig. (3): Receiver-operating characteristic (ROC) curve for prediction of Response using the EF%, GLS, QRS duration and BNP.

Items	Cut-off	Sen.	Spe.	PPV	NPV	AUC (C.I.95%)	p-value
EF%	**≥25**	80%	66.7%	44.4%	90.9%	0.790 (0.672-0.901)	0.026*
GLS	**≥ -10**	69%	53.3%	33.3%	84.2%	0.603 (0.513-0.691)	0.066
BNP	**≤330**	70%	63.3%	38.9%	86.4%	0.720 (0.622-0.823)	0.031*
QRS duration	**≥145**	70%	70%	43.8%	87.5%	0.817 (0.694-0.943)	0.015*

Receiver operating characteristics (ROC) curve was performed for EF% and demonstrated an area under the curve of 0.790 (0.672-0.901) with P value 0.026. The best cut off value for prediction of good CRT response was 25 with sensitivity 80% and specificity 66.7%. The table also clarified that, the BNP and demonstrated an area under the curve of 0.720 (0.622-0.823) with P value 0.031. The best cut off value for prediction of good CRT response was 330 with sensitivity 70% and specificity 63.3%. While, the QRS duration and demonstrated an area under the curve of 0.817 (0.694-0.943) with P value 0.015. The best cut off value for prediction of good CRT response was 145 with sensitivity 70% and specificity 70%.

DISCUSSION

In our population, we studied different parameters including age, gender, clinical status (NYHA Class), etiology of heart failure, QRS morphology and duration, basal BNP level, basal echo parameters, degree of desynchronization by tissue Doppler imaging, and GLS in the prediction of responding for CRT therapy.

Our results showed that we can depend on LBBB Morphology, NYHA class, basal ejection fraction (with cut-off value ≥25%), basal BNP (with cut-off value ≤330 pg/ml), clinical status (NYHA class), QRS duration (with cut-off value ≥145ms) LBBB morphology and etiology of heart failure in the prediction of the outcomes after CRT implantation. so we can use these measures to improve selection standards for patients who are candidates for CRT implantation, thus decreasing the frequent unsuitable implantation of biventricular pacing.

In terms of the age, gender, and etiology of heart failure as predictors of response to CRT, our findings showed that these variables play a significant role in the prediction of response, which is consistent with Peter et al., [14]. study of 433 cases with EF ≤35% and QRS >120 ms. They followed up on their patients for six years after CRT implantation and discovered that female gender and non-ischemic cause were associated with better outcomes. Guido et al., on the other hand, found no important role for age or gender in the prediction of responding to CRT in 64 cases of heart failure scheduled for CRT implantation [15, 16].

Our findings support previous research that suggests case characteristics including older age, male gender, right bundle branch block, and ischemic etiology are linked to less benefit from CRT[17, 18].

Molhoek et al., identified no differences in CRT responding in ischemic HF vs. idiopathic dilated cardiomyopathy classes, contrary to our findings and previous studies. In this analysis, however, response to CRT was characterized solely by an increase in NYHA functional class[5].

We looked at the impact of clinical status and basal NYHA class as a predictor, and our findings matched those of Vidal et al., who looked at 147 cases with NYHA Class III, IV, a large QRS complex, and low systolic function (LVEF of 24+ 7). The researchers concluded that cases in NYHA class III had better outcomes than cases in NYHA class IV, implying that this therapy could be effective earlier in the disorder progress[19].

In the current study, responders to CRT had significantly wider base-line QRS duration than non-responders group (152 ± 24.9 ms vs. 130.7 ±

24 ms respectively, P < 0.0001). The results are in agreement with prior data which revealed significant CRT benefit in HF patients with QRS ⩾ 150 ms[20, 21, 22].

A larger LVEF was correlated with echocardiographic responding in the Multicenter Automatic Defibrillator Implantation Trial with Cardiac Resynchronization Therapy (MADIT-CRT) study. However, a sub-analysis of results of the predictors of response to CRT trial (PROSPECT) found no difference in responders to CRT [23, 24]. Depending on research populations, there has been some contradictory evidence in the literature on the effect of baseline LV dimensions on CRT responding[22, 23, 24].

In contrast to our study, the MADIT-CRT trial showed that a larger LV was associated with echocardiographic responding, but sub-analysis of PROSPECT found no difference in responders[24, 25].

In our population, non-responders had greater base-line LV volume, lower LVEF and GLS. Our results are in agreement with Park et al. who established that base-line LV volume was a Predictor of echocardiographic responders to CRT[26].

Enlarged LV volumes may be a marker of HF progression and impairment of contractile function [27]. Smaller LVEDD and LVESD were found to be predictors of CRT response in this research, which was close to results from an earlier study that found LVEDD ≤ 67 mm was correlated with CRT responding after six months of follow-up[28].

When it came to the prognostic value of baseline LVEF, we discovered a connection with less extreme cases, such as in the MADIT sub-analysis, where cases with higher LVEF had a higher response rate. Direct comparisons of outcomes are difficult or impossible since various inclusion criteria and meanings of CRT responding were used[29].

Our results may donate information to new guidelines. Currently, CRT is most strongly recommended for symptomatic HF patients with a LVEF≤30% or 35% with a QRS duration≥150 ms and LBBB, with a weaker recommendation for cases without LBBB and in less prolonged QRS (120 or 130 ms)[30, 31, 32]. The most recent guidelines from the European Society of Cardiology focused on the importance of not implanting CRT in cases with QRS<130 ms based on the Echo CRT study[33, 34].

The systolic dyssynchronous index (Ts-SD-12) was able to predict the response to CRT in this research. Two broad, multicenter prospective studies - Predictors of Response to Cardiac Resynchronization Therapy (PROSPECT)[23] and the resynchronization therapy in narrow QRS study (ReThinQ)[35] used echocardiographic criteria to select patients for CRT and did not find association between echo-based indices of mechanical dyssynchrony and CRT gain, raising concerns about the need for echocardiography.

In our sample, the best cut-off value of GLS for good CRT response was -10% or more negative values. Contrary to our results, another study using the asynchrony index of two-dimensional strains and a segmented three-dimensional volume curve showed that this is not effective predictor of reverse remodeling[36].

Based on prior literature on the prognosis of patients with HF in hospitals, the author chose a GLS with predefined limit of 9% (or greater negative value) in order to be associated with a lower risk.

Miyazaki et al. studied 42 patients with HF who underwent CRT. BNP was measured at baseline and three to six months after CRT. He discovered that responders (n = 29, 69%) had significantly lower baseline levels and a significant greater decrease at the BNP levels than non-responders[37]. Which is consistent with our results.

Study Limitations:

The study had some limitations; limited sample size, heterogeneity of CRT responding definition, the short term follow up, absence of definite solution of the problem, and subjective evaluation of NYHA functional class. Finally, the site of implantation of CRT was not correlated with the degree of response.

CONCLUSIONS

We concluded that pre-implantation independent Predictors of good CRT response are LBBB morphology, septal to posterior wall mechanical delay, wide QRS duration, interventricular mechanical delay, NYHA functional class III, and lower levels of BNP. Large scale study is recommended for further verification of study results.

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