Original Article

Electrocardiographic Model to Predict Cardiac Resynchronization Therapy Response among Chronic Heart Failure Patients

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Background: Despite contemporary restrictive clinical and electrocardiographic selection criteria, up to one-third of chronic heart failure patients with implanted cardiac resynchronization therapy (CRT) are non-responders. Previous studies reported that some electrocardiographic patterns, such as the longer the intrinsicoid deflection (ID) in lead I, the higher the R wave amplitude in V_6, and other patterns may be helpful for CRT response prediction.

Objective: To establish a simplified model using electrocardiographic parameters as predictors of CRT response among chronic heart failure patients.

Materials and Methods: Eighty chronic heart failure patients meeting the current guideline recommendation for CRT implantation were enrolled in the present retrospective cohort study. The patients' clinical and electrocardiographic parameters at the time of CRT implantation and during follow-up were analyzed. The response to CRT was evaluated after six months of implantation, defined as a decrease in the left ventricular end systolic volume (LVESV) of 15% or more or an increase in the left ventricular ejection fraction (LVEF) of 10% or more.

Results: During a median follow-up period of 34 months, there were 45 (56.3%) responders. In multivariate analysis, the independent predictors for CRT response were the greater the reduction of the QRS complex duration after implantation (QRS post – QRS pre), the higher the time to ID in the lead I/QRS ratio (ID I/QRS), and the higher the difference in the amplitude of the R and S waves in lead V_1 and V_6 [(S1+R6) – (S6+R1)] (QRS post – QRS pre: adjusted odds ratio [OR] 0.97, 95% CI 0.94 to 0.99, p=0.004; ID I/QRS: OR 18.65, 95% CI 1.02 to 342.64, p=0.049; (S1+R6) – (S6+R1): OR 1.1, 95% CI 1.04 to 1.17, p=0.002). The new equation for calculating the predictive CRT response model, generated from multiple logistic regression analysis, was –3.414 – 0.035(QRS post – QRS pre) + 2.926(ID I/QRS) + 0.097[(S1+R6) – (S6+R1)]. The area under the receiver operating characteristic (ROC) curve for the new model for predicting CRT response was 0.853 (95% CI 0.767 to 0.939). A model score of more than 0.3 showed a sensitivity of 85.7% and specificity of 80% for the prediction of CRT response.

Conclusion: The new electrocardiographic model achieved a high sensitivity and specificity for the prediction of CRT response among chronic heart failure patients, who met the current guideline recommendation for CRT implantation.

Keywords: Cardiac resynchronization therapy, Electrocardiography, Heart failure, Responders, Model

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Current guidelines recommend cardiac resynchronization therapy (CRT) placement in chronic heart failure patients with the New York Heart Association (NYHA) class II-IV, persistent symptoms despite optimal medical therapy, a left ventricular ejection fraction (LVEF) of 35% or less, and QRS duration of 120 ms or more[1,2]. Regardless of the restrictive selection criteria, up to one-third of such patients are CRT non-responders[3,4]. Effective predictive parameters for identifying patients who have a tendency to achieve CRT response are important, but still imperfect.

Previous studies reported that some

electrocardiographic markers can represent interventricular dyssynchrony, left intraventricular dyssynchrony, or the latest activation region of the left ventricle, and may give rise to better independent predictors for CRT response[5-8]. The new interesting parameters included in the present study were the difference in time to intrinsicoid deflection (ID) in the aVL and aVF leads [(ID V_{aVL} – ID V_{aVF})/QRS (%)], in the V_1 and V_5 leads [(ID V_5 – ID V_1)/QRS (%)], the ratio of time to ID in lead I/QRS duration (ID I/QRS), the difference in time to ID between lead I and aVL (ID I – ID aVL), and the difference between the amplitude of the R and S waves in leads V_1 and V_6 [(S1+R6) – (S6+R1)][5-7]. These parameters may reflect patients who have ventricular electrical dyssynchrony, and might achieve a benefit from CRT.

The aim of the present study, conducted in symptomatic chronic heart failure patients who met the current guideline recommendation for CRT and who underwent implantation, was to evaluate the usefulness of those previously mentioned electrocardiographic parameters as predictors of CRT response. Furthermore, the authors aimed to modify the variables used in the equation and to establish a new model for predicting CRT response.

Materials and Methods

Study population and clinical data collection

The present study was a single-center retrospective cohort study of consecutive symptomatic chronic heart failure patients that underwent CRT implantation at a tertiary care academic hospital in Thailand between January 2005 and January 2019. The study was conducted using the database from a device clinic in the present study center. The study was approved by the Siriraj Hospital Institutional Review Board (COA no. Si 845/2018). According to the European Society of Cardiology (ESC) Guidelines 2016 and the American College of Cardiology (ACC) Guidelines 2017, the eligibility criteria were chronic heart failure patients with NYHA class II-IV, persistent symptoms despite optimal medical therapy, LVEF of 35% or less, and QRS duration of 120 ms or more. Exclusion criteria were patients with preceding implanted pacemakers, patients that underwent coronary angioplasty, coronary artery bypass, or valvular intervention less than six months before CRT implantation, patients lost to follow-up before their CRT response status could be evaluated, patients with missing important electrocardiographic or echocardiographic data, and patients that underwent unsuccessful left ventricular (LV) lead placement. Ischemic cardiomyopathy was confirmed by coronary angiography, magnetic resonance imaging (MRI), magnetic resonance angiography (MRA), a history of previous percutaneous coronary intervention (PCI), or coronary artery bypass grafting (CABG). Clinical and electrocardiogram (ECG) information during baseline and follow-up were retrospectively reviewed.

Electrocardiographic measurements

Standard 12-lead ECGs were recorded at a paper speed of 25 mm/second and amplitude of 10 mm/mV. Manual measurements were performed at the time before and immediately after CRT implantation by a cardiologist blinded to the CRT outcomes. Measurements included the QRS duration, R and S wave amplitude in V_1 and V_6, and time to ID in leads I, aVL, aVF, V_1, and V_5. From these parameters, the authors then calculated (S1+R6) – (S6+R1), (ID V_{aVL} – ID V_{aVF})/QRS (%), (ID V_5 – ID V_1)/QRS (%), ID I/QRS, and ID I – ID aVL. The time to ID was measured from the beginning of the QRS complex to the last peak of the R wave[6,9]. The reproducibility and reliability of the ECG measurements were assessed by intra- and interclass correlation coefficients (ICCs). For the R and S wave amplitude measurements, the ICC for the intra-observer variability was 0.993 (95% CI 0.972 to 0.998) and the ICC for the inter-observer variability was 0.990 (95% CI 0.96 to 0.998). For the time to the ID measurement, the ICC for intra-observer variability was 0.937 (95% CI 0.780 to 0.984) and the ICC for the inter-observer variability was 0.934 (95% CI 0.733 to 0.984). Left bundle branch block (LBBB) criteria refer to the 2018 ACC/AHA/HRS Guideline on Bradycardia and Cardiac Conduction Delay[10].

Echocardiographic evaluation

The echocardiographic parameters were evaluated at the time before and then reevaluated at least six months after CRT implantation. Measurements included LVEF calculated by the biplane Simpson method, left ventricular end systolic volume (LVESV) and left ventricular end diastolic volume (LVEDV) calculated by biplane disk summation, and left ventricular end systolic diameter (LVESD) and left ventricular end diastolic diameter (LVEDD) calculated by 2D-guided linear measurement in the parasternal long-axis view.

CRT responder definition

A CRT responder was defined as a decrease in LVESV of 15% or more or an increase in LVEF of

Table 1. Baseline patient clinical and echocardiographic characteristics

Baseline characteristics	Total (n=80) Mean±SD	Responders (n=45) Mean±SD	Non-responders (n=35) Mean±SD	p-value
Age (years)	63±12	62.6±12	64.1±12	0.508
Male/female; n (%)	54 (67.5)/26 (32.5)	27 (60.0)/18 (40.0)	27 (77.1)/8 (22.9)	0.104
BMI (kg/m^2)	23.95±4.7	23.8±5.1	24.2±4.2	0.884
ICM/NICM; n (%)	40 (50.0)/40 (50.0)	19 (42.2)/26 (57.8)	21 (60.0)/14 (40.0)	0.115
AF at implantation; n (%)	9 (11.3)	2 (9.0)	7 (20.0)	0.029*
NYHA class; n (%)				0.543
II	57 (71.2)	34 (75.6)	23 (65.7)	
III	19 (23.8)	10 (22.2)	9 (25.7)	
IV	4 (5.0)	1 (2.2)	3 (8.6)	
LVEF (%)	25.1±5.4	24.5±5.1	25.9±5.8	0.251
LVESV (mL)	159.7±67	163.4±71,2	155.5±62.6	0.611
LVEDV (mL)	214.7±81.8	216.7±87.2	212.3±76.2	0.813
Comorbidities; n (%)				
DM	32 (40.0)	18 (40.0)	14 (40.0)	1
HT	52 (65.0)	30 (66.7)	22 (62.9)	0.723
CKD	50 (62.5)	25 (55.6)	25 (71.4)	0.146
Cr (mg/dL)	1.3±0.7	1.3±0.8	1.5±0.5	0.004*
GFR (mL/minute/1.73 m^2)	56.8±26.5	61.4±27.4	50.9±24.4	0.046*
Medication use; n (%)				
BB	79 (98.8)	45 (100)	34 (97.1)	0.438
ACEI/ARB	60 (75.0)	39 (86.7)	21 (60.0)	0.006*
MRA	52 (65.0)	31 (68.9)	21 (60.0)	0.408
Digoxin	30 (37.5)	16 (35.6)	14 (40.0)	0.684
Diuretics	56 (70.0)	29 (64.4)	27 (77.1)	0.219

ACEI=angiotensin-converting enzyme inhibitor; ARB=angiotensin receptor blocker; AF=atrial fibrillation; BB=beta blocker; BMI=body mass index; Cr=creatinine; CKD=chronic kidney disease; DM=diabetes mellitus; GFR=glomerular filtration rate; HT=hypertension; ICM=ischemic cardiomyopathy; MRA=mineralocorticoid receptor antagonist; NICM=non-ischemic cardiomyopathy; NYHA=New York Heart Association; LVEDV=left ventricular end diastolic volume; LVEF=left ventricular ejection fraction; LVESV=left ventricular end systolic volume; SD=standard deviation

10% or more after six months of CRT implantation[4,11]. Patients who had heart failure death or hospitalized before this period were classified as non-responders.

Statistical analysis

IBM SPSS Statistics, version 24 (IBM Corp., Armonk, NY, USA) was used for statistical analysis. Categorical data were expressed herein as percentages, while continuous data were expressed as the mean ± standard deviation (SD) or median ± interquartile range (IQR). Comparisons between the two groups (CRT responders and non-responders) were performed using Pearson's chi-square for categorical data, while the independent t-test or Mann-Whitney U test was used for continuous data. Univariate and multivariate analysis were evaluated by using logistic regression analysis to identify the predictors for CRT response. After that, multiple logistic regression analysis was used to generate an equation. The receiver operating characteristic (ROC) curves for the equation were created and then the area under the curves were calculated. A log-rank test was used to compare the time to heart failure death or hospitalization between the two groups. A p-value of less than 0.05 was considered statistically significant.

Results

Patient characteristics

The baseline patient characteristics of the present study population are summarized in Table 1. Eighty patients were included in the present study, 54 (67.5%) of them male and the mean age at CRT implantation

Table 2. Baseline patient electrocardiographic characteristics

Baseline characteristics	Total (n=80) Mean±SD	Responders (n=45) Mean±SD	Non-responders (n=35) Mean±SD	p-value
LBBB; n (%)	44 (55.0)	32 (71.1)	12 (34.3)	0.001*
Baseline QRS duration (ms)	157.6±22	161.8±21.4	152.2±21.9	0.052
QRS post – QRS pre (ms)	–8.2±31.7	–18.8±26.6	5.4±32.8	0.001*
(ID V_{aVL} – ID V_{aVF})/QRS (%)	14.8±14.6	13.4±11.6	16.7±17.7	0.653
(ID V_5 – ID V_1)/QRS (%)	26.2±19.6	32.9±19.7	18.9±7.2	0.002*
ID I/QRS	0.5±0.2	0.56±0.2	0.43±0.16	0.002*
ID I – ID aVL (ms)	11.7±18	11.2±19	12.4±16.9	0.506
(S1+R6) – (S6+R1) (mm)	21.8±11.7	25.6±10.7	16.9±11.1	0.001*

ID=intrinsicoid deflection; LBBB=left bundle branch block; SD=standard deviation

was 63±12 years old. The number of patients with ischemic cardiomyopathy (40, 50%) was equal to those with non-ischemic cardiomyopathy (40, 50%). There were 57 (71.2%) patients in NYHA class II, 19 (23.8%) patients in NYHA class III, and four (5%) patients in NYHA class IV. The QRS morphology was LBBB in 44 (55%) patients and the mean baseline QRS duration was 158±22 ms. Overall, 11.3% of cases involved atrial fibrillation at the time of CRT implantation. Most patients were implanted with CRT-D (77, 96.3%) instead of CRT-P (3, 3.7%). The average baseline LVEF was 25.1±5.4%.

A median time from CRT implantation to echocardiographic re-evaluation was 14 months (IQR 8 to 22.5), with 45 (56%) CRT-responder patients. During a median follow-up period of 34 months (IQR 15.75 to 56.25), five (6.3%) patients died and 16 (20%) patients were hospitalized for heart failure. Among the 21 patients who died or had heart failure hospitalization, most were CRT non-responders (20, 95%). Comparing between the CRT responders and non-responders, there were no significant differences in age, gender, baseline NYHA functional classification, the heart failure etiology, baseline comorbidities, and baseline echocardiographic parameters. Non-responders tended to have a higher prevalence of atrial fibrillation at the time of CRT implantation (20% versus 9%, p=0.029), higher baseline creatinine (Cr) (1.5±0.5 versus 1.3±0.8, p=0.004), and lower glomerular filtration rate (GFR) (50.9±24.4 versus 61.4±27.4, p=0.046).

Electrocardiographic variables in responders and non-responders

The comparison of the electrocardiographic parameters between the two groups is shown in Table 2. There was no difference in baseline QRS duration between the two groups (p=0.052). Responders tended to have more of the LBBB-QRS complex morphology (71% versus 34%, p=0.001), whereby the greater the reduction of the QRS duration after implantation (–19 versus 1, p=0.001), the bigger the amplitude of [(S1+R6) – (S6+R1)] (24 versus 15, p=0.001), the higher the number for [(ID V_5 – ID V_1)/QRS (%)] (36.5 versus 15.4, p=0.002), and the higher the number for ID I/QRS (0.62 versus 0.45, p=0.002).

Clinical/electrocardiographic parameters and CRT response

The univariate and multivariate analysis of the variables for the prediction of CRT response are reported in Table 3. The clinical and ECG parameters were compared between the CRT responders and CRT non-responders. Univariate analysis showed that the CRT responders had significantly more of the LBBB-QRS complex morphology (odds ratio [OR] 4.72, p=0.001), whereby the greater the reduction of the QRS complex duration after implantation (OR 0.97, p=0.002), the higher the value of (ID V_5 – ID V_1)/QRS (OR 1.04, p=0.005), the higher the value of ID I/QRS (OR 44.79, p=0.003), and the higher the value of [(S1+R6) – (S6+R1)] (OR 1.08, p=0.002). Responders also tended to be female and to have a wider baseline QRS complex duration, but these did not meet statistical significance (OR 2.25, p=0.108; OR 1.02, p=0.55, respectively). Non-responders significantly had more atrial fibrillation (OR 0.079, p=0.002). Multivariate analysis showed that the independent predictors for CRT response were the greater the reduction of the QRS complex duration after implantation (adjusted OR 0.97, p=0.004), the higher the ID I/QRS (adjusted OR 18.65, p=0.049),

Table 3. Univariate and multivariate analysis of the predictors for CRT response

	Univariate analysis		Multivariate analysis	
	OR (95% CI)	p-value	Adjusted OR (95% CI)	p-value
Sex (female)	2.25 (0.84 to 6.05)	0.108		
HF etiology (ischemic)	0.49 (0.20 to 1.20)	0.117	0.541 (0.17 to 1.76)	0.307
AF	0.079 (0.016 to 0.38)	0.002*	1.17 (0.15 to 0.37)	0.880
LBBB	4.72 (1.82 to 12.20)	0.001*	1.32 (0.32 to 5.50)	0.708
Cr	0.57 (0.25 to 1.29)	0.174	0.49 (0.21 to 1.16)	0.104
GFR	1.02 (1.00 to 1.04)	0.085	1.01 (0.98 to 1.04)	0.480
Baseline QRS duration	1.02 (1.00 to 1.04)	0.055		
QRS post – QRS pre	0.97 (0.95 to 0.99)	0.002*	0.97 (0.94 to 0.99)	0.004*
(ID V_{aVL} – ID V_{aVF})/QRS	0.98 (0.95 to 1.02)	0.315		
(ID V_5 – ID V_1)/QRS	1.04 (1.01 to 1.07)	0.005*	1.02 (0.99 to 1.05)	0.256
ID I/QRS	44.79 (3.49 to 574.31)	0.003*	18.65 (1.02 to 342.64)	0.049*
ID I – ID aVL	1.00 (0.97 to 1.02)	0.753		
(S1+R6) – (S6+R1)	1.08 (1.03 to 1.14)	0.002*	1.1 (1.04 to 1.17)	0.002*

AF=atrial fibrillation; CI=confidence interval; Cr=creatinine; GFR=glomerular filtration rate; HF=heart failure; ID=intrinsicoid deflection; LBBB=left bundle branch block; OR=odds ratio

and the higher the [(S1+R6) – (S6+R1)] (adjusted OR 1.1, p=0.002).

ROC curves were constructed for the parameters of interest, referring to those significant variables from the multivariate analysis (Figure 1). Cut points for predicting CRT response were as follows: –5 ms for the difference between the pre- and post-implantation QRS duration, which yielded a sensitivity of 71% and specificity of 62.9%; a value of 55 for ID I/QRS, which yielded a sensitivity of 71.1% and specificity of 64.4%; and a value of 20 for (S1+R6) – (S6+R1), which yielded a sensitivity of 60.1% and specificity of 75.6%

CRT response model

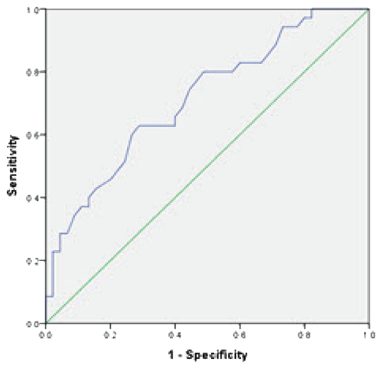
Multiple logistic regression analysis was used to identify predictors of CRT response and all the significant independent parameters were included to generate an equation. According to the relative effect of the included parameters in the regression model, the equation for calculating the predictive CRT response model was –3.414 – 0.035(QRS post – QRS pre) + 2.926(ID I/QRS) + 0.097[(S1+R6) – (S6+R1)]. The area under the ROC curve for this new equation in predicting CRT response was 0.853 (95% CI 0.767 to 0.939) and a value of more than 0.3 showed a sensitivity of 85.7% and specificity of 80% for the prediction of CRT response (Figure 2).

The Kaplan-Meier survival curve clearly showed that the event rate, referring to heart failure death and hospitalization, of CRT responders was much lower than that of CRT non-responders during a median follow-up period of 34 months (Figure 3).

Discussion

The present study investigated the ECG parameters as well as the clinical parameters for the prediction of CRT response in symptomatic chronic heart failure patients who met current guideline recommendations for CRT implantation. The authors found that during a median follow-up period of 34 months, the greater the reduction of the QRS duration after implantation, the higher the time to ID in the lead I/QRS ratio, and the higher the (S1+R6) – (S6+R1) value were all independent predictors for CRT response. These findings support the previous data[6,7,11,12]. Moreover, through multiple logistic regression analyses, the authors were able to generate an equation for calculating a predictive CRT response model, which was equal to –3.414 – 0.035(QRS post – QRS pre) + 2.926(ID I/QRS) + 0.097[(S1+R6) – (S6+R1)]. With this equation, a model score of more than 0.3 showed high sensitivity and specificity for the prediction of CRT response (85.7% and 80%, respectively).

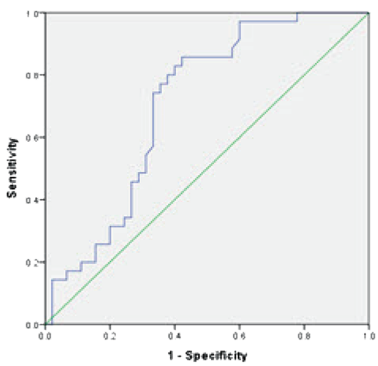
In the multiple logistic regression analyses, the time to ID in the lead I/QRS ratio or ID I/QRS had the highest relative effect for CRT response. For the ID I/QRS, Munoz et al[6] reported that this variable could express the delayed activation sequence to



The difference between the pre- and post-implantation QRS duration (QRS post - QRS pre)

ΔQRS	Cut point	Sensitivity	Specificity
Responders	< -5	71%	62.9%
Non-responders	≥ -5		

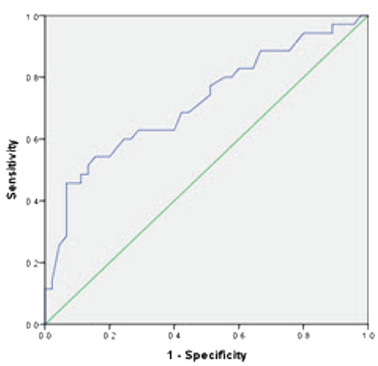
AUC = 0.713 (95% CI: 0.601–0.826)



The ratio of ID in lead I/QRS duration (ID I/QRS)

ID I/QRS	Cut point	Sensitivity	Specificity
Responders	> 55	71.1%	64.4%
Non-responders	≤ 55		

AUC = 0.707 (95% CI: 0.593–0.821)



(S1+R6) – (S6+R1)

(S1+R6) – (S6+R1)	Cut point	Sensitivity	Specificity
Responders	> 20	60.1%	75.6%
Non-responders	≤ 20		

AUC = 0.718 (95% CI: 0.603–0.834)

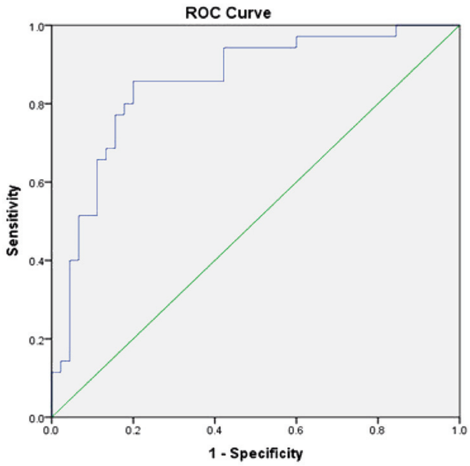
Figure 1. Receiver-operating characteristic (ROC) curves. The area under the curve (AUC) was calculated to evaluate the quality of each parameter as a CRT response predictor.

the lateral LV and reported it to be one of the most interesting predictors for CRT response. Regarding the difference between the amplitude of the R and S waves in lead V_1 and V_6 or (S1+R6) – (S6+R1). This variable was reported by Strauss et al[12] and later by Poposka et al[7] to be able to serve as a predictor of CRT response as it may represent a true LBBB from the LV conduction delay instead of from other causes, such as from LV hypertrophy.

The present study suggested that, in addition to the patient selection criteria for CRT implantation from current guidelines, this new model may be a helpful add-on measurement as a determinant factor for CRT response. These independent predictors for CRT response, as included in the equation, are likely to be representative markers for LV conduction delay. This may explain why patients with these markers, in other words patients with a higher value from this model, seem to have a better response rate to CRT.

Clinical implications

As aforementioned, despite the present restrictive



AUC = 0.853 (95% CI: 0.767–0.939)

	Cut point	Sensitivity	Specificity
Responders	> 0.3	85.70%	80%
Non-responders	≤ 0.3		

Figure 2. CRT response model receiver-operating characteristic (ROC) curve. CRT response model was calculated from −3.414 – 0.035(QRS post – QRS pre) + 2.926(ID I/QRS) + 0.097[(S1+R6) – (S6+R1)].

selection criteria, up to one-third of chronic heart failure patients meeting all those features are CRT non-responders. Hence, there are heterogeneities among those patients. According to the present study results, the reported model could be useful for physician decision-making, patient counseling, and may be helpful for improving the appropriate use of CRT. For example, those patients meeting CRT implantation indications and having a value from this model of more than 0.3 may gain the greatest benefit from CRT. On the contrary, for those with a value from this model of 0.3 or less, the tendency to achieve a CRT response is less likely, and the prognosis is much worse. For this reason, an early referral to heart transplantation or ventricular assist device evaluation may be considered in patients with such a low model score.

Limitation

First, the time to ID was obtained manually, and as a result, this may lead to a problem in the inter- and intra-observer reproducibility. Second,

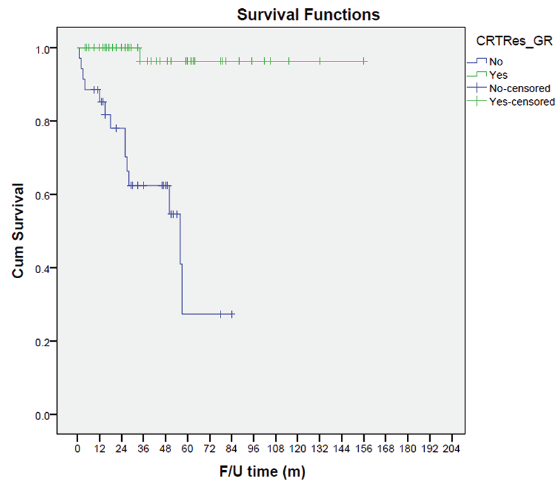


Figure 3. Kaplan-Meier survival curve of CRT responders and CRT non-responders.

the present study populations were symptomatic chronic heart failure patients meeting the current guideline recommendations for CRT implantation. Hence, the results might not be generalizable to other types of patients with CRT implantation, such as those not meeting the guideline criteria or those with pacemaker-induced cardiomyopathy. Finally, the CRT response criteria vary widely among studies, and in the present study, only echocardiographic responses were evaluated.

Conclusion

A new electrocardiographic model for the prediction of CRT response was detailed, consisting of variables that reflect LV conduction delay. A cut point of 0.3 from the model provides a useful add-on predictive value for CRT response in symptomatic chronic heart failure patients meeting the current guideline recommendations for CRT.

What is already known on this topic?

Previous studies have reported the beneficial electrocardiographic parameters, which represent ventricular dyssynchrony, are helpful for predicting CRT response in chronic heart failure patients. Some examples of those parameters are the longer the ID in lead I, the higher the R wave amplitude in V_6, and the ratio of time to ID in the lead I/QRS duration (ID I/QRS).

What does this study add?

This study reports a new electrocardiographic model for the prediction of CRT response. This model consists of parameters that reflect the LV conduction delay and provides a useful add-on predictive value for CRT response in symptomatic chronic heart failure patients meeting current guideline recommendations for CRT.

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Conflicts of interest

There is no conflict of interest and no direct funding for this study.

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