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Original Research Article

# Evaluation of the diastolic functions of the heart in patients with heart failure after Cardiac Resynchronization Therapy (CRT)

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ABSTRACT

**Background & Aim:** Improvement in systolic functions after CRT has been well-established, but the effect on Left Ventricular (LV) diastolic functions is variable and not well established. The aim of this study is to analyze the improvement in diastolic functions of the heart after CRT.

**Materials and Methods:** Total 67 cases of Heart Failure (HF) eligible for CRT (mean age, 62.5 ± 11.73 years; 54 males and 13 females) with Left Ventricular Ejection Fraction (LVEF) ≤35% or New York Heart Association (NYHA) Class II, III / Ambulatory IV (IVA) were included in the study. LVEF, pulsed-wave Doppler (PWD) derived transmitral filling indices (E and A wave velocities, E/A ratio), and peak early diastolic longitudinal myocardial velocity (E´) wave by tissue doppler were measured pre and post CRT and were compared.

**Observations and Results:** Left Ventricular Ejection Fraction (LVEF) increased >5% (responders) in 42 of 67 patients (62.6%) which was also associated with a reduction in pulsed-wave Doppler (PWD) derived indices that is E velocity, E/A ratio and E/E' ratio while in non-responders (LVEF<5%) the E velocity, E/A ratio, E' did not show significant change but E/E' reduced significantly after CRT.

**Conclusion:** Left Ventricular Diastolic functions improved significantly after CRT in responders but not in non responders.



## 1. Introduction

Cardiac resynchronization therapy (CRT) has been demonstrated to improve functional status, morbidity, and all-cause mortality in patients with heart failure and electrical dysynchrony.[1,2]

The benefits of CRT may not only result from an improvement in the Left Ventricular(LV) systolic function, but also from improvement in the diastolic function.

CRT has been shown to improve Left Ventricular functions reflected by a decrease in ventricular volumes and improvement in LV ejection fraction (LVEF).[3] The benefit of CRT on LV diastolic functions is not well characterized.

CRT improves symptom class, exercise capacity, quality of life, and systolic function.[4] The diastolic function of the LV is physiologically coupled to its systolic performance and is an important determinant of symptoms and outcomes in patients with LV systolic dysfunction.[5] Therefore, it can be hypothesized that CRT improves cardiac output not only by improved systolic emptying but also by better diastolic filling. The effects of CRT on LV diastolic functions are not well studied, and whether its improvement plays an important role in the mechanism of response to this therapy is less well-established.

Several studies have been conducted to evaluate LV Diastolic Functions in patients after CRT.

A study conducted by Sutton et al. in 2003 included 323 patients for studying the Diastolic parameters of early diastole (E), (A) wave velocities, E/A ratio, deceleration time (DT) and isovolumic relaxation time (IVRT).[6] No changes were seen in A, E/A, IVRT but DT increased only

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in the CRT group.

In another study by Waggoner et al. with 50 patients found a reduction in E, E/A and E/E’, increased DT, and Diastolic Filling Time (DFT) in patients with improvement in LV systolic function but no changes in E’ and Vp regardless of the systolic response.[7]

Shanks et al. in 2011 carried out their study on 188 patients with Heart failure (HF) receiving CRT, improvement in diastolic function was only observed in responders to CRT and patients with non-ischaemic etiology.[8]

Studies evaluating the effects of CRT on LV diastolic function using Pulse Wave Doppler-derived transmitral filling parameters have reported variable results; the mitral E- wave velocity or E/A ratio may not be significantly altered.[9–11]

A study by Alksoy et al. showed that improvement in diastolic function contributes to the overall benefit of CRT in responders.[12]

In a study by Doltra et al., which included 250 patients, confirmed the findings that LV diastolic function improves with CRT in echocardiographic responders (defined by a reduction in left ventricular (LV) end systolic volume of ≥ 15% at 1-year follow-up.[13]

All these studies using different parameters showed that CRT improves diastolic function (data are more controversial regarding relaxation); however, this seems to be dependent on improvement in systolic function.[14]

Thus, evaluation of the effects of CRT on LV function, exploring not only systolic but also diastolic properties, seems to be a more comprehensive approach to understanding the underlying mechanisms of clinical benefit of CRT. In this scenario, the current study aims to investigate this clinical situation of patients receiving CRT and how this affects the various diastolic echocardiographic parameters. Also, CRT data from the Indian population is sparse, and the current study aims to fill this data void.

CRT implantation has demonstrated an improvement in exercise capacity with peak oxygen consumption improvement in the range of 1 to 2 milliliters per kilogram per minute and an increase in 6MWD of 50-70 meters, along with a 10-point or greater reduction of heart failure symptoms on the 105- point Minnesota scale.[15–17] An approximately 30% decrease in hospitalizations and, more recently, a mortality benefit of 24% to 36% has been confirmed in large randomized trials.[18]

The safety and efficacy of CRT were first addressed in the year 2001 by both MUSTIC (Multisite Stimulation in Cardiomyopathies) and PATH-CHF (Pacing Therapies in Congestive Heart Failure) studies.[15] The MUSTIC trials evaluated the safety and efficacy of CRT in patients with advanced heart failure, ventricular dyssynchrony, and either normal sinus rhythm or atrial fibrillation.[19] These trials represent the first randomized, single-blind trials of CRT for heart failure.

## 2. Material and Methods

The present study is a single center, hospital based non-randomized prospective observational study to measure the effect of Cardiac Resynchronisation Therapy on the echocardiographic parameters of diastolic functions of the Left Ventricle.

The study was conducted at the Department of Cardiology, Fortis Escorts Heart Institute, New Delhi, from 1st September 2014 – 31st December 2015 (1 year 3 months) with follow up at 3 and 6 months. Patients with mean age, 62.5 ± 11.73 years (54 male and 13 female) admitted at Fortis Escorts Heart Institute, New Delhi, during the study period for first CRT implantation and satisfying the enrolment criteria of the study were included in the study.

### *2.1. Inclusion criteria*

1. Patients willing for CRT device implantation for acceptable indications of HF.
   a) Patients of Heart Failure, NYNA Class II, III / Ambulatory IV (IVA) despite optimal medical therapy.

   b) Left ventricular systolic dysfunction, LVEF ≤35%.
   c) Wide QRS complex ≥ 120 msec.
2. Patient willing to participate in the study.
3. Willing for follow-up.

### *2.2. Exclusion criteria*

1. Not willing to participate
2. Moribund patient
3. Severe multiorgan dysfunction
4. Non-ambulatory patients
5. Acute coronary syndrome (less than 3 months)
6. Recent coronary revascularization (during the last 3 months)
7. Patients in persistent AF
8. Treatment-resistant hypertension
9. Severe obstructive pulmonary disease
10. Reduced life expectancy not associated with cardiovascular disease (less than one year

### *2.3. Methodology*

Total 70 cases eligible for CRT were enrolled and were evaluated as follows:

Pre-intervention assessment done.

Inclusion/Exclusion Criteria applied.

Three cases were excluded from the study. One who couldn’t come for follow-up, one patient died, and the third was lost during follow up.

Intervention: CRT device (CRT-P or CRT-D) implantation.

Approval for the study was taken from the Ethics Committee. Informed consent was taken from all the study participants to participate in the study. The investigator also signed a confidentiality statement on the informed consent before recruitment. A detailed history and clinical examinations were done and recorded on a predesigned proforma. Clinical parameters of breathlessness were evaluated by NYHA classification [20] at baseline and follow-up. ECG was done at baseline and during follow-up.

The subjects were advised to follow-up at 3 and 6 months after implantation. They were free to report sooner in case of worsening of symptoms or any other complaints. At follow-up, clinical and echocardiographic study parameters were recorded.

Echocardiographic parameters were recorded on the Phillips i33 echocardiography machine by experienced operators. The following parameters were recorded- Left Ventricular Ejection Function (LVEF), PWD-derived transmitral filling indices measured were early diastolic (E) and atrial (A) wave velocities, the E/A ratio, and E´wave by tissue doppler imaging(TDI). E´at both the lateral and medial mitral annulus was recorded using pulsed wave Tissue Doppler Imaging (TDI), and the mean was taken for the calculation. E/E´was also measured.

### 2.4. *Responder vs non-responder*

For comparing Diastolic echo parameters, patients were grouped according to their clinical and echocardiographic response. Clinical Responders were those who improved their NYHA class of 1 or more. Echocardiographic Responders were those who increased LVEF > 5%, and the rest were non-responders.

#### 2.4.1. *Drugs*

The subjects in this study were on optimal medical therapy as per ACC/AHA Heart failure management guidelines. [21–23] Other necessary cardiac medications such as antiarrhythmics, antiplatelets, and anticoagulants were also given and recorded.

### 2.5. *Data analysis and statistics*

Data analysis and statistics were done with the help of IBM® SPSS® Statistics version 20.0 for windows.

Categorical variables are expressed as numbers and percentages; continuous variables are expressed as mean ± standard deviations.

A comparison of the clinical and echocardiographic parameters was made prior to and after CRT was performed using paired and unpaired Student t test and Pearson correlations as appropriate. p value of $< 0.05$ was taken as statistically significant.

## 3. Observations & Results

All the 67 patients enrolled in the study based on the inclusion criteria were evaluated as responders or nonresponders and LVEF, as well as diastolic echocardiographic measurements, were taken at the baseline and on follow-up at 3 and 6 months.

The mean age of the sample population (n = 67) was 62.5 ± 11.73 years. In this study, the Male: Female sex ratio of the enrolled subjects is approximately 4:1 (n = 54 for males and n = 13 for females). There were no significant differences between responders and nonresponders by their age, gender, medication for HF, follow up period, PR interval, QRS duration and etiology of LV dysfunction.

Table 1 shows the evaluation of diastolic functions in all patients under study. E velocity at 3 months did not show any significant change, but at 6 months there was a significant improvement in the E wave velocity. The E/A ratio improved significantly at both 3 and 6 months of follow up. E´value did not show any significant change from baseline on the other hand E/E´, which represents the LA pressure was reduced significantly at 3 and 6 months of follow up.

Table 2 and Table 3 show that the E velocity was significantly reduced in the responder at both 3 and 6 months but not in non-responder group; E/A velocity was also reduced significantly in the responder group only at both 3 and 6 months. LV relaxation parameter of E´did not reduce significantly in both responder and non-responder group, although there was a trend toward improvement in the responder group. E/E´Which represents the LA pressure was reduced significantly in both responder and non-responder group.

The LV diastolic function when compared with the responder against non responder, there was no significant difference in any of the parameters at baseline; however, 6 months post-implant, the E velocity E/A and E/E´was significantly improved in the responder group while only E/E´improved significantly in non responder group.

## 4. Discussion

Heart failure is a growing problem, especially in aging societies posing a great burden on the healthcare system. A high percentage of deaths are attributed to heart failure and its complications owing to the rising costs of healthcare management and hospitalizations. Management of heart failure should be decided based on its etiology and stage (advancement) of heart failure. Apart from optimal medical therapy like angiotensin-converting enzyme inhibitors, diuretics, and β-blockers each patient with an ejection fraction (EF) ≤35% should be considered for implantable cardioverter-defibrillator (ICD) based on approved guidelines and Patients with symptomatic heart failure (class III and IV), EF ≤35%, and QRS ≥120

**Table 1:** Diastolic functions pre and post CRT in all patients

| Diastolic functions | Mean | SD | p |
|---|---|---|---|
| Baseline E | 81.75 | 24.9 | |
| E AT 3 MTHS | 76.87 | 24.1 | 0.251 |
| E AT 6 MTHS | 71.85 | 20.1 | 0.0125 |
| Baseline A | 54.8 | 23 | |
| A AT 3 MTHS | 56.7 | 22.5 | 0.629 |
| A AT 6 MTHS | 59.7 | 23.7 | 0.226 |
| Baseline E/A | 1.75 | 0.893 | |
| E/A AT 3 MTHS | 1.49 | 0.561 | 0.023 |
| E/A AT 6 MTHS | 1.4 | 0.629 | 0.005 |
| Baseline E´ | 5.67 | 1.59 | |
| E´AT 3 MTHS | 5.78 | 1.526 | 0.24 |
| E´AT 6 MTHS | 5.78 | 1.523 | 0.71 |
| Baseline E/E´ | 16.33 | 2.997 | |
| E/E´AT 3 MTHS | 13.3 | 2.499 | 0.0001 |
| E/E´AT 6 MTHS | 11.94 | 2.801 | 0.0001 |

E: Early Diastolic transmitral filling velocity A: Atrial wave velocity
E': Peak early diastolic longitudinal myocardial velocity
SD: Standard Deviation

**Table 2:** Diastolic functions in responders

| Diastolic functions | | Responder | | |
|---|---|---|---|---|
| | | Mean | SD | p |
| | Baseline | 82.25 | 22.921 | |
| E Velocity | 3 MTHS FU | 70.89 | 16.67 | 0.0047 |
| | 6 MTHS FU | 68.56 | 14.793 | 0.0001 |
| | Baseline | 53.73 | 23.576 | |
| A Velocity | 3 MTHS FU | 57.23 | 23.56 | 0.45 |
| | 6 MTHS FU | 59.67 | 23.411 | 0.182 |
| | Baseline | 1.79 | 0.893 | |
| E/A | 3 MTHS FU | 1.42 | 0.499 | 0.005 |
| | 6 MTHS FU | 1.33 | 0.55 | 0.002 |
| | Baseline | 5.65 | 1.399 | |
| E´ | 3 MTHS FU | 5.79 | 1.46 | 0.196 |
| | 6 MTHS FU | 5.92 | 1.453 | 0.08 |
| | Baseline | 16.58 | 3.038 | |
| E/E´ | 3 MTHS FU | 12.96 | 2.231 | 0.001 |
| | 6 MTHS FU | 11.33 | 2.423 | 0.001 |

E: Early Diastolic transmitral filling velocity A: Atrial wave velocity
E': Peak early diastolic longitudinal myocardial velocity
SD: Standard Deviation

ms should be offered cardiac resynchronization therapy (CRT).[24,25] Numerous studies support the benefits of CRT for the improvement of LV systolic functions, but the studies on its benefit on diastolic functions are few.

In this study, load dependent PWD derived parameters (E wave, A wave, E/A ratio) indicating diastolic filling pattern showed significant improvement in echo responders only while E/E' indicating left atrial pressure showed improvement in both the echo responder and non responder group. There were no significant improvement in load independent diastolic parameter of E'.

E/A in this study at baseline was 1.75±0.893, which improved to 1.4±0.629 at 6 months of follow up and was statistically significant, however when grouped into responder and non- responder, E/A in responder reached significance at follow up p=0.002 but in non- responder E/A did not reach significance p=0.719. Waggoner et al.[26] Kammoun et al.[27] reported similar results that CRT decreases the mitral E wave velocity and the E/A ratio only in those patients who exhibit significant decreases in LV volumes and significant improvement in LVEF. These results are consistent with the preload-dependency of PWD-derived mitral inflow parameters.

E´, the load independent LV relaxation parameter in this study did not show any significant difference at 6 months of follow up p=0.71; this was true even the subjects were

**Table 3:** Diastolic functions in non responders

| Diastolic functions | | Non responder | | |
|---|---|---|---|---|
| | | Mean | SD | p |
| E Velocity | Baseline | 80.13 | 32.176 | |
| | 3 MTHS FU | 82.56 | 32.34 | 0.838 |
| | 6 MTHS FU | 83.27 | 30.591 | 0.566 |
| A Velocity | Baseline | 58.87 | 21.51 | |
| | 3 MTHS FU | 59.17 | 21.89 | 0.97 |
| | 6 MTHS FU | 60.07 | 25.672 | 0.787 |
| E/A | Baseline | 1.6 | 0.91 | |
| | 3 MTHS FU | 1.73 | 0.704 | 0.499 |
| | 6 MTHS FU | 1.67 | 0.816 | 0.719 |
| E´ | Baseline | 5.73 | 2.187 | |
| | 3 MTHS FU | 5.73 | 1.792 | 1 |
| | 6 MTHS FU | 5.73 | 1.792 | 1 |
| E/E´ | Baseline | 15.47 | 2.774 | |
| | 3 MTHS FU | 14.07 | 3.058 | 0.008 |
| | 6 MTHS FU | 14.07 | 3.058 | 0.011 |

E: Early diastolic transmitral filling velocity A: Atrial wave velocity
E’: Peak early diastolic longitudinal myocardial velocity
SD: Standard deviation

divided into responder (p=0.08) and non- responder (p= 1) group. Thus, despite the benefits observed in LV diastolic filling after CRT, measurements of global LV relaxation was not favorably altered and there were no changes in the relatively load independent measurements of TDI derived E´, regardless of the response in LV volumes or LVEF. Wagonner et al. also reported similar findings, and he inferred that it is possible that recovery of LV relaxation is delayed after CRT and thus not evident at a short-term follow up.[26]

E/E´, the ratio between peak early Filling (E) and peak early diastolic longitudinal myocardial velocity (E’) reflects the LA pressure, in this study E/E´at baseline was 16.3±2.9 this decreased to 11.9±2.8 at 6 months of follow up p=0.001 when grouped into responder and non responder E/E´decreased significantly in both the groups, similar findings were reported by Waggoner et al, Jansen et al.[28] and Alksoy et al.[29] in their study.

## 5. Limitations of study

The limitations of this study were as follows:

It was a single centre study, not a multicenter study. The current study is an observational and uncontrolled investigation, and the low sample size might interfere with the results. This study was not a randomized trial of Echocardiography in heart failure patients receiving CRT versus control, and therefore, the results are at the best speculative and not conclusive.

## 6. Conclusions

This study was undertaken to study the efficacy of Cardiac Resynchronisation Therapy in patients of heart failure in terms of echocardiographic improvement of diastolic function and functional improvement in terms of NYHA class for which the study was adequately powered. There is robust data from well-organized, randomized controlled trials on the efficacy of CRT demonstrating its effect on echocardiographic LV systolic function and functional outcome; however, the diastolic function is not so well studied. Lately, many single center well conducted studies have been published demonstrating the effect of CRT on the diastolic function of LV.

This study has reported similar results in the study population. It was a sicker population with 41.8% of patients in functional class NYHA IVA. Clinical responders in the study were 76.1% at 3 months and 77.6% at 6 months. The diastolic parameters of E wave velocity, E/A wave ratio, and E/E´improved significantly post CRT implantation in responders; however, E´did not show any significant difference post CRT. The author concludes that CRT appears promising and this study supports the efficacy of CRT in the population studied in terms of improving a patients clinical symptoms, improvement in LVEF and improvement in cardiac relaxation as shown by improvement in diastolic function of LV.


## 7. Conflicts of Interest

None.

## 8. Source of Funding

None.

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