PROCEDURAL SUCCESS RATE OF CARDIAC RESYNCHRONIZATION THERAPY AND DEFIBRILLATOR IMPLANTATION IN HEART FAILURE PATIENTS

Qamar-Uz-Zaman Bhatti, Adeel-ur-Rehman*, Usman Iqbal**, Imran Fazal, Mohammad Bilal Siddique, Azhar Ali Chaudhry

Armed Forces Institute of Cardiology/National Institute of Heart Diseases/National University of Medical Sciences (NUMS) Rawalpindi Pakistan, *Rawalpindi Institute of Cardiology (RIC) Rawalpindi Pakistan, **Combined Military Hospital Abbottabad/ National University of Medical Sciences (NUMS) Pakistan

ABSTRACT

Objective: To determine the success rate of cardiac resynchronization therapy and defibrillator implantation in heart failure patients.

Study Design: Descriptive cross sectional study.

Place and Duration of Study: This study was conducted at AFIC-NIHD from 1st Jul 2014 to 31st Dec 2014.

Material and Methods: A total of 45 patients were included in the study that underwent CRT-D implantation. The procedural success was noted in the catheterization laboratory (cath lab) and in wards, where patients were managed after CRT-D implantation. Procedural success was based on three criteria: 1) class improvement in NYHA class, $2 \ge 5$ % improvement in ejection fraction (EF) and 3) conversion of Left bundle branch block (LBBB) into normal QRS complexes.

Results: Most of patients 15 (33.0%) were between 57-62 years of age. 34 (75.6%) were males and 11 (24.4%) females. the mean age of the patients was 53.6 ± 7.8 years (range 35 - 67 years).

Pre-procedure mean EF was 24.71% and post procedure mean EF was 31.33%. Prior to procedure 33 (73.3%) patients were in NYHA Class III and 12 patients (26.7%) were in NYHA Class IV. 93.0% patients showed improvement in NYHA class. EF improved in 93.0% patients and 89.1% patients converted to normal QRS complexes after CRT-D implantation. The overall combined success rate was 93.0%.

Conclusion: The procedural success rate of CRT-D was high and should be offered to the patients with heart failure who are non responder to medical treatment whenever the facility is available.

Keywords: CRT-D (cardiac resynchronization therapy and defibrillator), Heart failure.

This is an Open Access article distributed under the terms of the Creative Commons Attribution License (http://creativecommons.org/licenses/by/4.0), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

INTRODUCTION

Heart failure (HF) has become a major disease burden in last two decades due to aging population, growing incidence of diabetes, hypertension, obesity, improved survival after Myocardial linfarction (MI) and success in preventing sudden cardiac death^{1,2}. Medical therapies, such as angiotensin converting enzyme (ACE) inhibitors. beta blockers. and spironolactone have markedly improved both symptom control and overall survival in patients with heart failure. Unfortunately, medical therapy is not completely effective in prevention or reversing the progression of HF².

Simultaneous pacing of both ventricles

(biventricular or BiV pacing) or of one ventricle in patients with bundle branch block, benefits some patients with Heart Failure. This approach is referred to as cardiac resynchronization therapy (CRT)³⁻⁹. It resynchronizes the contractions of the heart's ventricles by sending tiny electrical impulses to the heart muscle, which in turn improves mechanical performance of heart, leading to improved systolic and diastolic left ventricular (LV) function⁹⁻¹¹. Patients with advanced heart failure who are not benefited from optimal medical treatment are candidates for cardiac resynchronization therapy (CRT). This is achieved with a device, designed only for pacing or combined with an ICD (implantable Cardioverter defibrillator) called CRT-D (cardiac resynchronization therapy and defibrillator)^{9,10}. CRT-D has the additional function to quickly

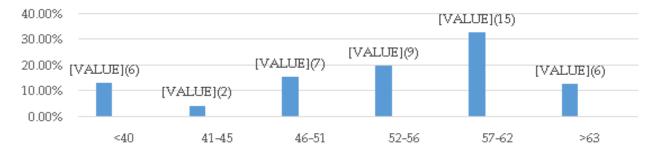
Correspondence: Dr Qamar-uz-zaman Bhatti, AFIC/NIHD Rawalpindi, Pakistan (*Email: qamarbhatti1789@gmail.com*)

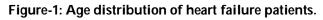
terminate an abnormally fast, life-threatening heart rhythm. CRT and CRT-D have become increasingly important therapeutic options for patients with moderate and severe heart failure with low EF¹¹. The success rate for CRT ranged from=88.0% to 92.0% in clinical trials¹². No similar study has been conducted in our set up so far.

The rationale of this study was to assess the

cardiac condition in which life expectancy is less than 6 months, RBBB on ECG, Asymptomatic patients with reduced LVEF≤35%,Patients who were unwilling for CRT-D implantation. Success of the CRT-D was ascertained on the basis of 3 criteria:

• One class Improvement in NYHA class of heart failure accessed clinically on 6th post CRT-D implantation day.





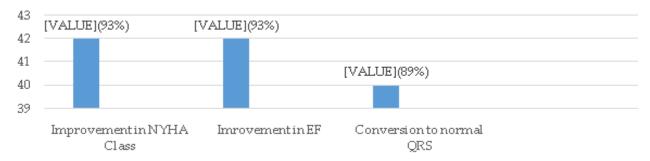


Figure-2: Success rate of CRT-D in heart failure patients.

success rate of CRT-D in our set up. This will help and guide us about advanced management of heart failure patients in our population who are refractory to optimal medical management.

MATERIAL AND METHODS

This descriptive study was conducted at AFIC/NIHD Rawalpindi for the duration of six months, from 1st Jul 2014 to 31st Dec 2014. A total of 45 patients of heart failure were included in the study on the basis of non-probability purposive sampling. Inclusion criteria were: Age limit 20-75 years ,Heart failure of NYHA class II to IV, LVEF ≤ 35%,LBBB with QRS >120ms,Patients of both Genders. Exclusion criteria included: Chronic non

- Conversion of LBBB to normal QRS complexes determined on ECG Immediately after CRT-D implantation.
- 5% or more improvement in EF measured by echocardiography on 6th post CRT-D implantation day.

A written informed consent was taken from all the patients enrolled in the study. Patients who presented with heart failure in the emergency department, their ECG was done immediately and promptly managed by resident cardiologist, then shifted toward where echocardiography was done to determine EF and ventricular dyssynchrony. Patients were counseled about advantages and disadvantages of CRT-D, written informed consent for the procedure was obtained and patients were CRT-D implantation prepared for after arrangement of CRT-D device. The procedure was performed by the consultant cardiologist in catheterization laboratory. The correct implantation was ensured by the satisfactory positions of leads in RA, RV and CS, desired pacing, sensing thresholds and successful DC shock delivery on inducing ventricular tachycardia (VT).

Data Analysis

Data was analyzed in SPSS version 21. Mean standard deviation were used for and quantitative variables i.e. age, EF, and width of QRS complex while frequency and percentage was used for qualitative variables like gender and success rate. Effect modifiers like age, gender, NYHA class were controlled by stratification. Post stratification Wilcoxon Signed Ranks test was applied to determine the improvement in NYHA class, and the paired t-test was applied to determine the improvement in QRS width and EF. *P*-value was significant i.e. <0.05.

RESULTS

A total of 45 patients were included in the study, out of which 34 (75.6%) were male and 11 (24.4%) were female. The mean age of the patients was 53.60 \pm 7.887 years (range 35-67 years) (fig-1).

Out of 45 patients 33 (73.3%) were in NYHA Class III and 12 patients (26.7%) were in NYHA Class IV. 40 (89.0%) patients showed conversion of LBBB into normal QRS complexes. Preprocedure the mean QRS width was 132.22 msec and post-procedure the mean QRS width was 118.11 msec. The two other success criteria i.e. one class improvement in NYHA Class and \geq 5% improvement in EF were each achieved in 42 (93.0%) patients (fig-2).

Pre procedure mean EF was 24.71% and post procedure mean EF was 31.33%. Overall successful response to CRT-D was seen in 42 (93%) patients (fig-3).

DISCUSSION

With advancing technologies and new methods of intervention, CRT-D has evolved as a great new d evelopment in the management of patients with heart failure, especially those refractory to optimal medical treatment. Recent trials are also favoring CRT-D over medical therapy because of the better outcome. There were not enough studies done in our country due to lack of centers and expertise capable of CRT-D implantation in heart failure patients.

This Retrospective study was carried out among 45 patients of symptomatic heart failure. Three success criteria in our study were: 1) the conversion of LBBB into normal QRS complexes, 2) improvement in EF by 5% or more 3) improvement in NYHA class by one. The first criteria i.e; conversion of LBBB into normal QRS complexes was met in 89.0% patients while other

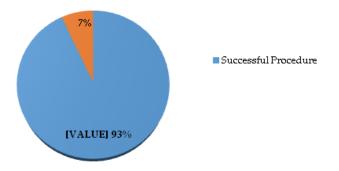


Figure-3: Overall success rate of CRT-D in heart failure patients.

two criteria (improvement in EF by 5% or more and improvement in NYHA class by one) were achieved in 93.3% patients, proving the overall beneficial effects of CRT-D in heart failure patients. These findings were in agreement with CARE-HF, MIRACLE and COMPANION trial data which support the use of CRT-D in heart failure patients having LBBB with QRS duration \geq 120 to 140 msec, NYHA class III or IV and EF \leq 35 percent, to reduce symptoms, duration of hospitalizations and overall survival6,13,14.

In the CARE-HF trial, there were 813 patients (mean age 67) with NYHA class III or IV HF (94 percent class III and 6 percent IV), an

LVEF ≤35 percent (mean 25%), and QRS prolongation (mean QRS duration 138 msec) who underwent CRT implantation⁶. The benefits noted were improvement in EF up to 3.7% at 3 months. Our study was done on 45 patients, with mean age of 53.60 ± 7.887 years. Out of 45 patients 33 (73.3%) were in NYHA class III and 12 patients (26.7%) were in NYHA class IV. The mean QRS width was 132.22 msec, pre-procedure mean EF was 24.7% and post procedure mean EF was 31.33%. In our study, improvement in EF was 6.6%, which is more than that seen in CARE-HF trial. MADIT-CRT trial has proved that CRT-D is more beneficial as compared to ICD alone¹⁵ while our study only evaluated the performance of CRT-D.

CONCLUSION

The success rate of CRT-D implantation was found to be very high (93.0%) among patients with heart failure who have LBBB, $EF \le 35$ % and NYHA Class III or IV. Patients with heart failure especially those who were non responder to maximally optimized medical treatment benefitted with CRT-D device. So, CRT-D, whenever the facilities are available, should be offered to the patients of refractory heart failure and who are unfit for cardiac transplantation.

There is also need for future trials to compare the outcome of CRT-D with routine anti heart failure treatment.

CONFLICT OF INTEREST

This study has no conflict of interest to declare by any author.

REFERENCES

- Schocken DD, Benjamin EJ, Fonarow GC :Prevention of heart failure: A scientific statement from American Heart Association Councils on Epidemiology and Prevention, Clinical Cardiology, Cardiovascular Nursing, and High Blood Pressure Research; Quality of Care and Outcomes Research Interdisciplinary Working Group. Circulation 2008; 117: 2544.
- Auricchio A, Abraham WT. Cardiac resynchronization therapy: current state of the art: cost versus benefit. Circulation 2004; 109: 300.
- 3. Leclercq C, Hare JM. Ventricular resynchronization: current state of the art. Circulation 2004; 109:
- Jarcho JA. Resynchronizing ventricular contraction in heart failure. N Engl J Med 2005; 352: 1594.
- 5. Burkhardt JD, Wilkoff BL. Interventional electrophysiology and cardiac resynchronization therapy: delivering electrical therapies for heart failure. Circulation 2007; 115: 2208.
- Cleland JG, Daubert JC, Erdmann E. The effect of cardiac resynchronization on morbidity and mortality in heart failure. N Engl J Med 2005; 352: 1539.
- Cleland JG, Daubert JC, Erdmann E. Longer-term effects of cardiac resynchronization therapy on mortality in heart failure the CArdiac REsynchronization-Heart Failure (CARE-HF) trial extension phase]. Eur Heart J 2006; 27: 1928.
- Bristow MR, Saxon LA, Boehmer J. Cardiac-resynchronization therapy with or without an implantable defibrillator in advanced chronic heart failure. N Engl J Med 2004; 350: 2140.
- 9. Williams LK, Ellery S, Patel K. Short-term hemodynamic effects of cardiac resynchronization therapy in patients with heart failure, a narrow QRS duration, and no dyssynchrony. Circulation 2009; 120: 1687.
- Abraham WT, Hayes DL. Cardiac resynchronization therapy for heart failure. Circulation 2003; 108: 2596.
- 11. Epstein AE, DiMarco JP, Ellenbogen KA. ACC/AHA/HRS 2008 Guidelines for Device-Based Therapy of Cardiac Rhythm Abnormalities: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Writing Committee to Revise the ACC/AHA/NASPE 2002 Guideline Update for Implantation of Cardiac Pacemakers and Antiarrhythmia Devices): developed in collaboration with the American Association for Thoracic Surgery and Society of Thoracic Surgeons. Circulation 2008; 117: e350.
- Hunt SA, Abraham WT, Chin MH, Feldman AM, Francis GS, Ganiats TG et al: ACC/AHA 2005 guideline update for the diagnosis and management of chronic heart failure in the adult: summary article. Circulation. 2005; 112: 1825–1852; J Am Coll Cardiol 2005; 46: 1116–1143.
- Bristow MR, Saxon LA, Boehmer J. Cardiac-resynchronization therapy with or without an implantable defibrillator in advanced chronic heart failure. N Engl J Med 2004; 350: 2140.
- 14. Abraham WT, Fisher WG, Smith AL. Cardiac resynchronization in chronic heart failure. N Engl J Med 2002; 346: 1845.
- Singh JP, Klein HU, Huang DT. Left ventricular lead position and clinical outcome in the multicenter automatic defibrillator implantation trialcardiac resynchronization therapy (MADIT-CRT) trial. Circulation 2011; 123: 1159.