Case Report

Feasibility, Safety, and Mid-Term Efficacy of Cardiac Resynchronization Therapy in Patients with Severe Heart Failure and Ventricular Conduction Delay: Chulalongkorn Experience

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Background: *Heart failure is a major and growing public health problem in developed and developing countries. Despite major advances in medical therapy, morbidity and mortality remain high. Cardiac resynchronization therapy (CRT) has been proposed as an adjunctive therapy in patients with drug-refractory heart failure and ventricular conduction delay. Short and long-term studies have demonstrated the clinical benefits of CRT.*
Objective: *The present study was designed to assess the feasibility, safety, and mid-term efficacy of CRT in patients with severe heart failure and ventricular conduction delay in the institute.*
Material and Method: *Ten patients with severe heart failure in New York Heart Association (NYHA) functional class III or IV with left ventricular ejection fraction (LVEF) < 35%, QRS duration > 120 ms with left bundle branch block morphology received CRT. At baseline, and 6 months after implantation, the following parameters were evaluated: NYHA class, QRS duration, LVEF, N-terminal pro-brain natriuretic peptide (NT-pro BNP) level, 6-minute walking distance, SF-36 quality-of-life (QOL) score, and number of heart failure visit.*
Results: *All clinical parameters improved significantly at 6 months. NYHA class decreased from 3.5 $\pm$ 0.5 to 2.4 $\pm$ 0.7 ($p < 0.01$). QRS duration decreased from 145 $\pm$ 22 ms to 126 $\pm$ 6 ms ($p < 0.01$). LVEF increased from 21 $\pm$ 6% to 31 $\pm$ 12% ($p < 0.01$). NT-pro BNP level decreased from 2503 $\pm$ 1953 pg/ml to 767 $\pm$ 342 pg/ml ($p < 0.01$). The 6-minute walking distance increased from 153 $\pm$ 122 m to 278 $\pm$ 128 m ($p < 0.01$). QOL score improved from 66 $\pm$ 14 to 98 $\pm$ 25 ($p < 0.01$). The number of heart failure visits was reduced from 3.8 $\pm$ 3.7 per year to 0.5 $\pm$ 0.8 visit per year ($p < 0.01$). Seventy percent of patients were free of heart failure visit for one year after implantation. One patient had sudden cardiac death eleven months after implantation. There was no procedure-related mortality. One patient had left ventricular lead dislodgement 3 months after implantation.*
Conclusion: *In the present study, CRT was safe and effective in improving heart failure symptom, functional status, LV function, and quality of life. CRT also reduced heart failure hospitalization in the presented severe heart failure and ventricular conduction delay patients.*

Keywords: *Cardiac resynchronization therapy, Heart failure, Ventricular conduction delay, Biventricular pacing*

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Heart failure is a major cause of hospitalization, morbidity, and mortality in patient's aged more than 60 years. Despite major advances in medical therapy, morbidity and mortality remain high[1]. Cardiac resynchronized therapy (CRT) was introduced in the early 1990s, and dramatically developed over time. CRT is a special pacing system that stimulates both ventricles simultaneously (biventricular pacing). Biventricular pacing corrects the dyssynchronous contraction of the ventricles and thus improves cardiac performance. Early studies have demonstrated the improvement of hemodynamic[2,3] and left ventricular systolic function[4]. Nonrandomized and randomized studies showed that CRT significantly improved symptoms, exercise tolerance, and quality of life[5,6]. The CRT has also demonstrated favorable effects on disease progression and significantly improved outcomes in subgroup of heart failure patients[7,8]. In these trials, the inclusion criteria were not much different: 1) moderate to severe heart failure (New York Heart Association, NYHA class III, IV) despite optimized medical therapy; 2) depressed left ventricular ejection fraction (LVEF); and 3) wide QRS complex (duration > 120 ms) with left bundle branch block morphology.

In Thailand, the prevalence of heart failure has been increasing over the decade. The demand for effective treatment for refractory heart failure has also been rising. The present study aimed to assess the mid-term efficacy of CRT in patients with end-stage systolic heart failure and ventricular conduction delay in the institute.

Material and Method

Patients

Consecutive heart failure patients hospitalized between Nov 2001 and April 2005 were included if they met the following inclusion criteria: 1) severe heart failure (NYHA class III or IV) due to either ischemic or non-ischemic cardiomyopathy; 2) LVEF of 35 percent or less; 3) QRS interval more than 120 ms with left bundle branch block morphology. Patients received all standard treatments for heart failure, which included diuretics, angiotensin converting enzyme inhibitors or angiotensin receptor blockers, and usually digitalis and beta blockers. The doses of these medications were unchanged for at least one month.

Patients were excluded if they had a recent history of atrial and ventricular arrhythmia, recent myocardial infarction, recent or pending coronary revascularization, severe valvular disease, dependence of intravenous inotropics, and conventional indications for pacemaker implantation.

Clinical evaluations

Patients meeting the inclusion criteria underwent the following evaluations: estimation of NYHA functional class; 6-minute walking test [9]; a QRS duration measuring from a 12-lead electrocardiogram; two-dimensional Doppler-flow echocardiography, which included measurement of LVEF using the biplane Simpson's rule, the internal end-diastolic dimension, and degree of mitral regurgitation; quality-of-life (QOL) evaluation using SF-36 questionnaire [10]; numbers of heart failure visit (emergency room visit or hospitalization due to worsening heart failure and require intravenous diuretic for symptom control for one year prior to CRT); N-terminal pro-brain natriuretic peptide (NT-pro BNP) level(Roche Diagnostics)[11]. The NT-pro BNP level was required for patients who enrolled after September 2004 when the test was first available in Thailand.

CRT implantation

After baseline clinical evaluations, patients underwent CRT implantation. The standard right atrial lead and right ventricular lead were positioned in the high right atrium and in the septal region of the right ventricle respectively. For positioning the LV pacing lead, a coronary sinus venogram was obtained during balloon occlusion. The lead was inserted through the coronary sinus along the 8 Fr-guiding catheter. The lead was positioned as far as possible in the venous system, preferably in the posterolateral vein (Fig. 1). The leads were connected to a biventricular pacemaker programmed in DDD-R mode. The atrioventricular (AV) interval was adjusted to maximize the mitral inflow duration using pulsed wave Doppler-echocardiography.

After CRT implantation, patients were hospitalized for five days. Patients returned for clinical follow-up at one, three, and six months after implantation. During this time, all the medications for heart failure were kept unchanged. Baseline parameters were reevaluated at six months after CRT. The number of heart failure visits was reevaluated at one year after CRT.

Statistical analysis

All data analyses were performed using the Statistical Package for Social Science (SPSS 13.0) software (SPSS Inc., Chicago, Illinois). Data were expressed as mean $\pm$ standard deviations. Comparison of the

Table 1. Baseline characteristics of the end-stage heart failure patients

Patient no.	Sex	Age (Y)	Etiology	NYHA class	EF, (%)	PR, ms	QRS, ms	Med
1	F	73	DCM	3	26	180	126	BB, ARB, Di
2	M	76	ICM	3	28	186	142	BB, ARB, Di
3	F	72	DCM	4	21	183	123	BB, ARB, Di, Dig
4	F	65	ICM	3	24	196	188	ARB, Di, Spi
5	M	64	DCM	3	11	199	156	ACEI, Di, BB, Spi
6	F	73	DCM	4	26	127	127	BB, Di, Spi, Dig
7	M	52	DCM, AICD for VT	3	20	186	124	BB, ACEI, Di, Amio
8	F	67	DCM	4	20	202	175	ACEI, Di, Spi, Dig
9	F	73	ICM	4	30	196	152	Di, Spi, Hydra
10	F	71	ICM	4	10	200	140	Di, Spi, Dig, IV inotropic

ICM = ischemic cardiomyopathy; DCM = dilated cardiomyopathy; AICD = automatic implantable cardioverter defibrillator; VT = ventricular tachycardia; EF = left ventricular ejection fraction; BB = beta blocker; ARB = angiotensin receptor blocker; ACEI = angiotensin-converting enzyme inhibitor; Di = diuretic (furosemide); Dig = digitalis; Spi = spinorolactone; Hydra = hydralazine; Ami = amiodarone

changes from baseline to the six-month visit (or one-year visit for numbers of heart failure visit) was evaluated for the significance by nonparametric, Wilcoxon signed ranks test. A p-value of < 0.05 was considered significant.

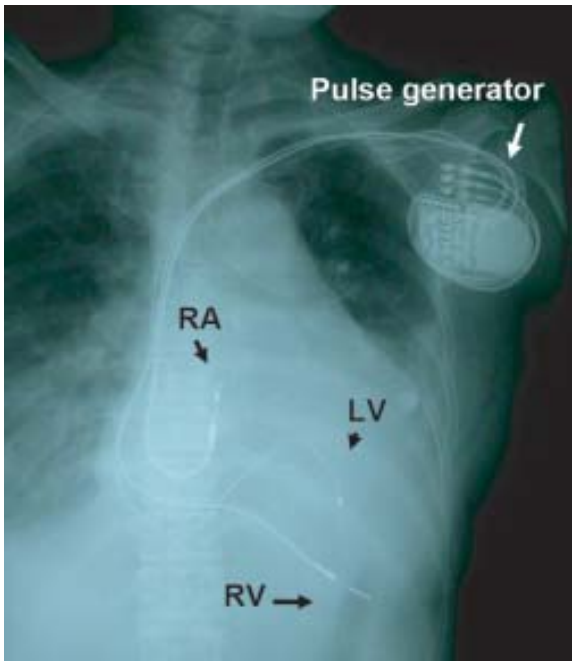


Fig. 1 Chest radiography showed CRT (biventricular pacing) system
RA = right atial lead, RV = right ventricular lead, LV = left ventricular epicardial lead inserted into posterolateral branch of coronary vein through coronary sinus

Results

Patient population

Between Nov 2001 and April 2005, consecutive twelve heart failure patients met the inclusion criteria. One was in chronic atrial fibrillation and was excluded from the present study. Eleven patients underwent CRT implantation. Because of one unsuccessful implantation, ten patients were included (M:F = 3:7, mean age 68.6 $\pm$ 7.0 years). Four patients (40%) had ischemic heart failure. The mean NYHA class was 3.5 $\pm$ 0.5. All patients had severe LV dysfunction with the mean LVEF of 21.6 $\pm$ 6.0% (11% -30%). The mean QRS duration on surface electrocardiogram was 145 $\pm$ 22 ms (123-188 ms). Baseline characteristics are shown in Table 1.

CRT implantation

All patients received the biventricular DDD-R pacemakers (Insync model 8042, Medtronic Inc (n = 6) and Contak renewel TR, Guidant (n = 4)). Patient no. 7 had dilated cardiomyopathy and previously undergone single chamber automatic implantable cardioverter-defibrillator implantation (AICD) for ventricular tachycardia. In this patient, a new CRT system was implanted. All patients were in sinus rhythm during implantation. There was no procedure-related complication. All patients had pacemaker interrogated at one, three, and six months after implantation. Early LV lead dislodgement did not occur but late LV lead dislodgement

occurred in patient no. 8 at three months after implantation and required surgical LV lead implantation.

Clinical follow-up

All patients completed the six-month follow-up.

NYHA class: The mean NYHA class improved from 3.5 ± 0.5 to 2.4 ± 0.7 ($p < 0.01$) (Fig. 2A). Three patients had two functional class improvements. Five patients had one functional class improvement. Two patients had no functional class improvement (Fig. 2B). According to NYHA class change, the response rate was 80%.

QRS duration: At baseline, mean QRS duration was 145 ± 22 ms, and significantly decreased to 126 ± 6 ms at 6-months follow-up ($p < 0.01$) (Fig. 3A).

Left ventricular ejection fraction: LVEF was 21 ± 6% at baseline and improved significantly at 6-month follow-up (31 ± 12%, $p < 0.01$) (Fig. 3B).

NT-pro BNP level: The data were available in five patients. The mean of NT-pro BNP level was 2503 ± 1953 pg/ml at baseline and decreased to 767 ± 342 pg/ml ($p < 0.01$) at 6-month follow-up (Fig. 3C).

Six-minute walking test: Only nine patients completed the test. The mean distance was 153 ± 122 m at baseline and increased significantly to 278 ± 128 m ($p < 0.01$), which had improved on average 82% at 6-month follow-up (Fig. 4A).

Quality-of-life (QOL)SF-36 score: QOL score at baseline was 66 ± 14 and increased to 98 ± 25 at 6- month follow-up ($p < 0.01$) (Fig. 4B). Six patients improved > 50% in QOL score.

Number of heart failure visits: One patient died suddenly eleven months after CRT. Only nine patients completed one-year follow-up. The average number of heart failure visits decreased from 3.8 ± 3.7 to 0.5 ± 0.8 visit/year after implantation ($p < 0.01$) (Fig. 4C). Seven patients were free of heart failure visit for one year after implantation.

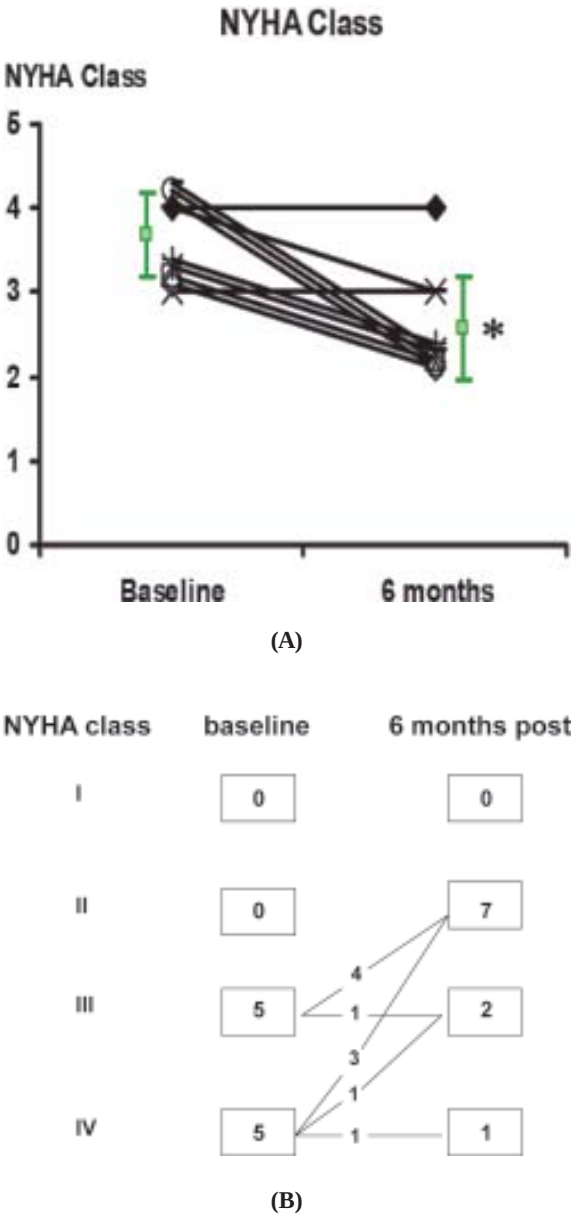
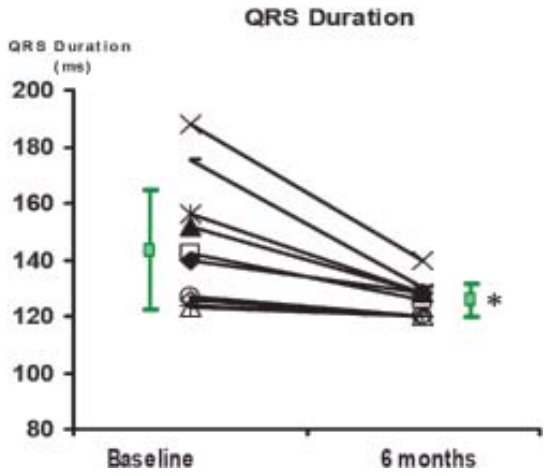


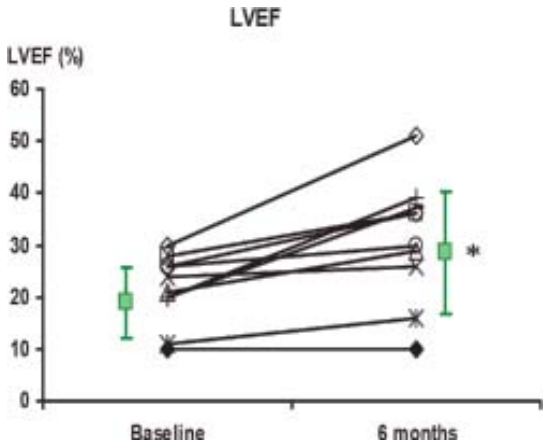
Fig. 2 Individual patient and Mean ± SD of NYHA class (A), distribution of patients according to NYHA class (B) at baseline and 6 months after CRT
* $p < 0.01$

Long-term follow-up

The mean follow-up duration was 24 ± 15 months (range 11 to 54). During follow-up, one patient had sudden cardiac death eleven months after implantation. Nine patients had a follow-up for more than one year. The survival rate at one year was 90%. Seven patients were free of heart failure visit for one year after implantation. Patient no 1 was later discovered to have colon cancer and underwent successful operation without cardiovascular complication. Patient no 2 had high LV lead pacing threshold 34 months post implantation. He underwent pacemaker replacement along with surgical LV lead implantation three years after enrollment. Patient no 8 had markedly improved cardiac performance and dramatically decreased in number of heart failure visits (from ten to zero visit/year). Chest radiography showed markedly reducing in heart size



(A)



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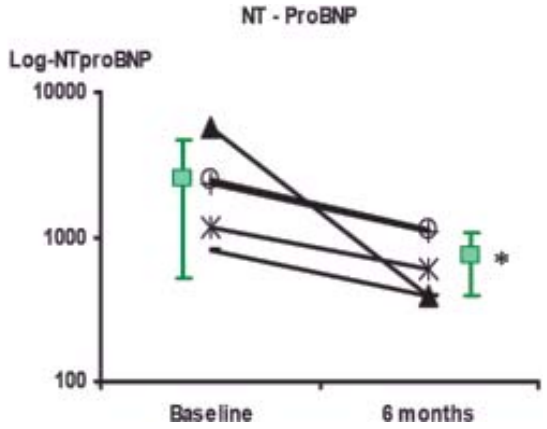
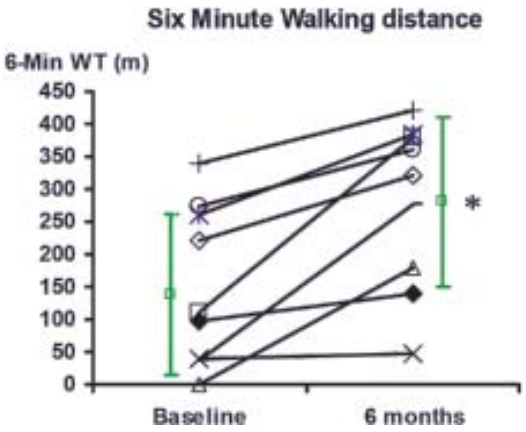
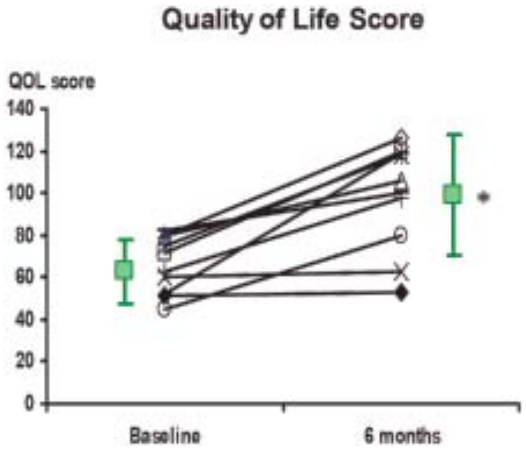


(C)

Fig. 3 Individual patient and Mean ± SD of QRS duration (A), LVEF (B), NT-pro BNP level (C) at baseline and 6 months after CRT
* $p < 0.01$



(A)



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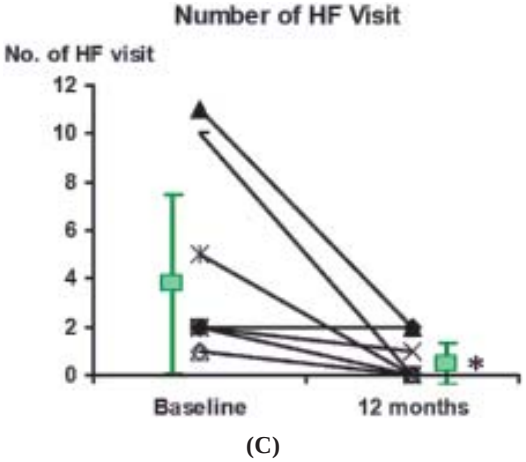

(C)

Fig. 4 Individual patient and Mean ± SD of six-minute walking distance (A), quality of life score (B), numbers of heart failure visit (C) comparing baseline and 6 months after CRT
* $p < 0.01$

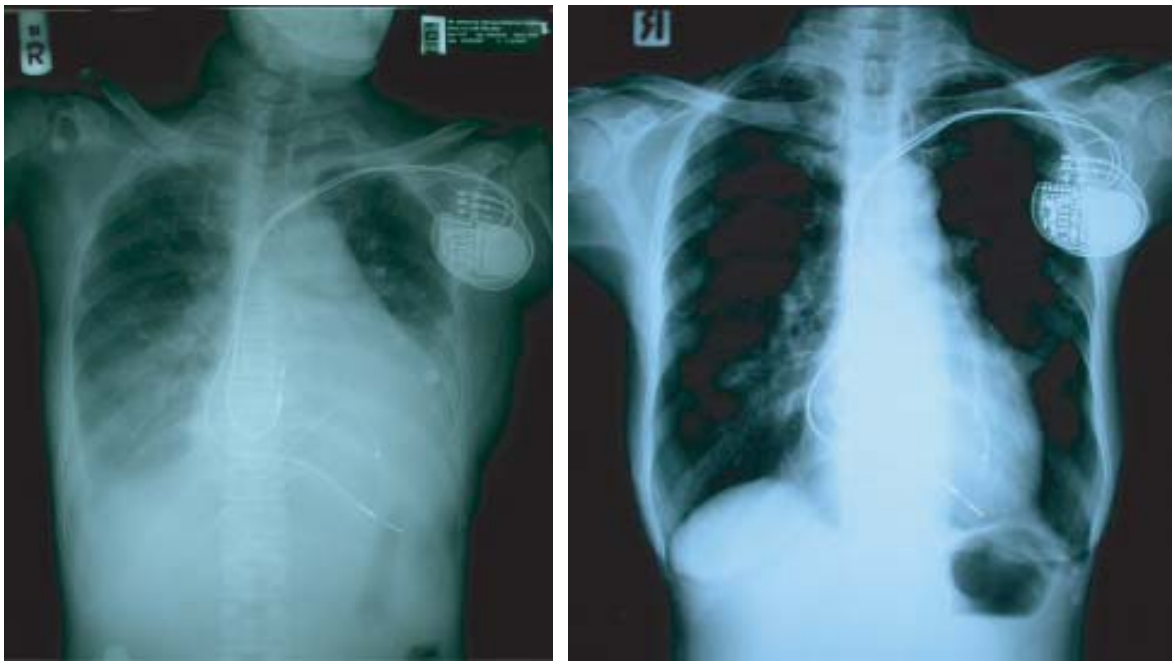

Fig. 5 Chest radiography showed markedly reducing in heart size and pulmonary congestion one day and six months after implantation in patient no 8

and pulmonary congestion (Fig. 5). Patient 10 developed reversible, acute renal failure from NSAID usage.

Discussion

The results of the present study indicated that CRT improved heart failure symptoms, functional status, and cardiac function in patients with severe heart failure and prolonged QRS interval at mid-term follow-up. CRT resulted in an improvement in symptoms (NYHA class), functional status (6-minute walking distance), accompanied by improvement in more objective parameters including QRS duration, LVEF, and NT-pro BNP level. The NT-pro BNP level, which had a strong correlation with heart failure mortality[12,13], was also significantly decreased. In addition, annual heart failure visit decreased significantly after pacemaker implantation and quality of life was improved. This beneficial effect became apparent at a very early stage and persisted throughout follow-up. The authors did not report short-term effect because the maximum and stable effect was demonstrated at 4-6 months after CRT[14,15]. The response rate in terms of NYHA improvement was 80%. This observation was in agreement with previous studies[15-17]. For example, Reuter et al demonstrated that 18% of 102 consecutive patients undergoing CRT did not improve in NYHA functional class and quality-of-life score. Similarly, in the MIRACLE trial, 20% of patients did not experience an improvement in symptoms. Some explanations for the non-responders were probably related to the type of underlying heart disease and limitation of implantation technique. Idiopathic dilated cardiomyopathy had a better response to CRT than ischemic cardiomyopathy. The multiple regional wall motion abnormality and hibernating myocardium from ischemia might be the cause. Two of our non-responders were suffering from ischemic heart failure. Another explanation for non-responder was the limitation of the implantation technique. Regarding the LV lead implantation technique via coronary sinus system, it was not always possible to place the LV lead to the mid-posterolateral region of left ventricle to gain the optimal benefit of CRT.

The longest follow-up in the present study was 54 months (range 11 to 54). One of the present cases had sudden cardiac death eleven months after implantation. The 1-year survival rate was 90%. This patient would have had the benefit of the combination of CRT and defibrillator (CRT-D) in mortality reduction according to the Comparison of Medical Therapy, Pacing, and Defibrillation in Heart Failure (COMPANION) trial[7].

Regarding safety, the risks associated with

the implantation of a CRT device are relatively small and similar to the risks and complications associated with the implantation of a conventional pacemaker or defibrillator[6-8]. Transvenous implantation of a left ventricular lead for CRT is accomplished via the coronary sinus and its tributaries. The specific risks associated with implantation of a left ventricular lead include coronary sinus dissection and perforation (1%), lead dislodgement (5%), and extra-cardiac stimulation (5%). In the present study, lead dislodgement occurred in one case. There was no procedure-related mortality.

In conclusion, the authors' experience with the first ten cases with CRT in severe heart failure patients gave the good impression of benefit at mid-term follow-up. The CRT is safe and effective in improving cardiac symptom, functional status, LV function and quality of life in the presented severe heart failure and ventricular conduction delay patients.

Limitation

The main limitations of the present study were that it was observational study and had a limited number of patients. Nevertheless, the results are encouraging and supported by the results of the recent large randomized clinical trials.

Acknowledgment

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ประสิทธิภาพและความปลอดภัยของ cardiac resynchronization therapy ในผู้ป่วยหัวใจล้มเหลวขั้นรุนแรงที่มี ventricular conduction delay

บัญชา ศันสนีย์วิทยกุล, สุรพันธ์ สิทธิสุข, สมเกียรติ แสงวัฒนาโรจน์, สมชาย ปรีชาวัฒน์, สมนพร บุญญรัตเวช สองเมือง

ภูมิหลัง: *หัวใจล้มเหลวเป็นปัญหาทางการแพทย์ที่สำคัญและเพิ่มมากขึ้นทั้งในประเทศที่พัฒนาและกำลังพัฒนา ถึงแม้ว่าการรักษาหัวใจล้มเหลวจะมีความก้าวหน้าอย่างมากแต่อัตราทุพพลภาพและอัตราการเสียชีวิตยังสูง cardiac resynchronization therapy (CRT) ถูกใช้เป็นการรักษาเสริมในผู้ป่วยหัวใจล้มเหลวขั้นรุนแรงที่มี ventricular conduction delay มีหลักฐานแสดงให้เห็นถึงประโยชน์ในทางคลินิกของ CRT ทั้งในระยะสั้นและระยะยาว*

วัตถุประสงค์: *การศึกษานี้ต้องการประเมินความเป็นไปได้ ความปลอดภัยและประสิทธิภาพของ CRT ในผู้ป่วยหัวใจล้มเหลวขั้นรุนแรงที่มี ventricular conduction delay ของโรงพยาบาลจุฬาลงกรณ์*

วัสดุและวิธีการ: *ผู้ป่วยหัวใจล้มเหลวขั้นรุนแรงที่มี New York Heart Association (NYHA) functional class III หรือ IV ที่มี การทำงานของหัวใจห้องซ้าย (LVEF) ลดลงต่ำกว่า35% และ QRS ที่มีลักษณะแบบ left bundle branch block และกว้างมากกว่า120 ms. ได้รับการใส่เครื่อง CRT หกเดือนภายหลังการใส่เครื่อง CRT มีการประเมินตัววัดต่าง ๆ ต่อไปนี้คือ NYHA class, ความกว้างของ QRS complex, การทำงานของหัวใจห้องซ้าย (LVEF), ระดับของ N-terminal pro-brain natriuretic peptide (NT-pro BNP), ระยะทางที่เดินได้ในหกนาที, คะแนนคุณภาพชีวิต (SF36), และจำนวนครั้งของการเข้ารับการรักษาในโรงพยาบาลด้วยภาวะหัวใจล้มเหลวเปรียบเทียบกับก่อนใส่เครื่อง*

ผลการศึกษา: *พบว่าค่าเฉลี่ยของตัววัดต่างๆ ดีขึ้นทุกค่าเมื่อเวลาหกเดือน เทียบกับก่อนใส่เครื่อง CRT NYHA class ลดลงจาก 3.5 $\pm$ 0.5 เป็น 2.4 $\pm$ 0.7 ($p < 0.01$) ความกว้างของ QRS complex ลดลงจาก 145 $\pm$ 22 ms เป็น 126 $\pm$ 6 ms ($p < 0.01$) การบีบตัวของหัวใจห้องซ้ายเพิ่มจาก 21 $\pm$ 6% เป็น 31 $\pm$ 12% ($p < 0.01$) ระดับ NT-pro BNP ลดลงจาก 2503 $\pm$ 1953 pg/ml เป็น 767 $\pm$ 342 pg/ml ($p < 0.01$) ระยะทางที่เดินได้ในหกนาทีเพิ่มจาก 153 $\pm$ 122 m เป็น 278 $\pm$ 128 m ($p < 0.01$) คะแนนคุณภาพชีวิตเพิ่มจาก 66 $\pm$ 14 เป็น 98 $\pm$ 25 ($p < 0.01$) จำนวนครั้งของการเข้ารับการรักษาในโรงพยาบาลด้วยภาวะหัวใจล้มเหลวลดลงจาก 3.8 $\pm$ 3.7 ครั้งต่อปีเป็น 0.5 $\pm$ 0.8 ครั้งต่อปี ($p < 0.01$) หนึ่งปีภายหลังได้รับ CRT เจ็ดสิบเปอร์เซ็นต์ของผู้ป่วยไม่ต้องเข้ารับการรักษาภาวะหัวใจล้มเหลวในโรงพยาบาล ผู้ป่วยหนึ่งรายเสียชีวิตเฉียบพลันหลังได้ CRT นานสิบเอ็ดเดือน ไม่มีผู้ป่วยเสียชีวิตจากการใส่ CRT มีผู้ป่วยหนึ่งรายที่สายกระตุ้นหัวใจห้องล่างซ้ายเลื่อนหลังการใส่ได้สามเดือน*

สรุป: *การศึกษานี้แสดงว่า CRT ในผู้ป่วยหัวใจล้มเหลวขั้นรุนแรงของโรงพยาบาลจุฬาลงกรณ์ที่มี ventricular conduction delay เป็นการรักษาที่มีความปลอดภัยและมีประสิทธิภาพในการลดอาการหัวใจล้มเหลว เพิ่มสมรรถภาพของร่างกาย และแรงบีบตัวของหัวใจห้องซ้าย นอกจากนี้ยังเพิ่มคะแนนคุณภาพชีวิตและลดจำนวนครั้งของการเข้ารับการรักษาภาวะหัวใจล้มเหลวในโรงพยาบาล*