



# Epicardial Left Ventricular Lead Implantation for Cardiac Resynchronization Therapy Midterm Results

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## Abstract

**Introduction:** Cardiac Resynchronisation Therapy (CRT) grows as an effective treatment modality due to its serious symptomatic recovery and improved survival rates in patients with left ventricle systolic dysfunction refractory to medical treatment and serious intra-interventricular dyssynchronisation. The purpose of our report is to discuss the midterm results of the epicardial LV pacing lead implantation via mini left lateral thoracotomy when conventional transvenous implantation failed.

**Materials and Methods:** From March 2014 to April 2015, 14 epicardial leads were implanted surgically at two different centers with the same surgical team. All patients who had cardiac heart failure functional class III or IV according to New York Heart Association (NYHA), dilated ischemic or non-ischemic cardiomyopathy dysfunction defined as LVEF <35% and a left bundle branch block (LBBB) (QRS duration >120 ms) were preselected by the cardiologists.

**Results:** Fourteen patients (71% male) with a mean age of  $73.1 \pm 6.6$  years underwent epicardial LV lead placement. Mean follow-up time was  $16.5 \pm 3.3$  (12 to 23) months, mean intensive care unit stay was  $24.7 \pm 23.9$  (8 to 102) hours and mean hospitalization time was  $82.7 \pm 46.4$  (52 to 240) hours. All patients had left bundle-branch block (LBBB) with mean (SD) QRS duration of  $178.7 \pm 18.1$  ms (range 156 ms to 210 ms). NYHA, QRS interval and LVEF values of patients before implantation and during follow-up showed statistically significant difference (preprocedural vs. postprocedural 2<sup>nd</sup> month mean NYHA values  $3.14 \pm 0.3$  vs.  $1.7 \pm 0.4$ ,  $p < 0.001$ , preprocedural vs. postprocedural mean QRS duration (ms)  $178.7 \pm 18.1$  vs.  $133.7 \pm 4.7$ ,  $p < 0.001$ , preprocedural vs. postprocedural 2<sup>nd</sup> month mean LVEF (%)  $22.9 \pm 2.2$  vs.  $34 \pm 2.8$ ,  $p < 0.001$ ) whereas pacing threshold, left ventricle impedance and LVEDd values showed no statistically significant difference. There were no operative deaths but one patient (7.1%) died at postoperative 18<sup>th</sup> month because of non-cardiac reason. One patient had pneumonia (7.1 %) and one patient had bleeding (7.1 %) (Not required re-exploration).

**Conclusion:** Transvenous lead implantation approach is the first line treatment choice for patients who need CRT implantation. If there is a presence of non suitable conditions for that approach, epicardial lead implantation should come to mind without enforcing transvenous approach.

**Keywords:** Cardiac resynchronization therapy; Left ventricular lead implantation; Arrhythmia

## Introduction

Despite all the pharmacologic progress, mortality and morbidity rates are very high in chronic cardiac failure patients due to left ventricle systolic dysfunction. Cardiac Resynchronisation Therapy (CRT) grows as an effective treatment modality due to its serious symptomatic recovery and improved survival rates in patients with left ventricle systolic dysfunction refractory to medical treatment and serious intra-interventricular dyssynchronisation [1,2].

Left ventricular pacing lead implantation is generally achieved via transvenous approach by coronary sinus cannulation and implantation of the lead to the major cardiac vein [3]. This approach cannot be used in 5% to 10% of patients because of their anatomic variations such as absence of suitable lateral coronary vein branches or tortuosity of coronary sinus or target branches or dissection of coronary sinus during procedure [4]. Although endocardial left ventricle pacing via transeptal approach is defined as an alternative way in patients who had an unsuccessful attempt of transvenous approach, surgical epicardial lead placement becomes a better alternative with its reliability, shorter implantation time and better selection of optimal pacing area [5-7].

The purpose of our report is to discuss the midterm results of the epicardial LV pacing lead

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**Table 1:** Demographic variables of the patients.

HT: Hypertension; COPD: Chronic Obstructive Pulmonary Disease; DM: Diabetes Mellitus; CRF: Chronic Renal Failure; AF: Atrial Fibrillation; ICD: Implantable Cardioverter Defibrillator; NYHA: New York Heart Association; LVEF: Left Ventricule Ejection Fraction; LVEDd: Left Ventricule End Diastolic diameter

	Patient's n (%)
Age (Years)	62-82 (73 ± 6,6)
Gender (Male/Female)	10/4 (71,4% / 28,6%)
HT	8 (57,1)
COPD	7 (50)
DM	8 (57,1)
CRF	0 (0)
AF	2 (14,3)
Previous Cardiac Surgery	5 (35,7)
Previous ICD Implantation (CRT-D upgrade)	6 (42,9)
Aetiology	
Ischemic cardiomyopathy	11 (78,6)
Dilated cardiomyopathy	3 (21,4)
NYHA	
Class III	12 (85,7)
Class IV	2 (14,3)
LVEF (%)	20 – 26 (22,9 ± 2,2)
LVEDd (mm)	66-74 (69,5 ± 2,2)
QRS duration (ms)	156-210 (178,7 ± 16,1)

implantation via mini left lateral thoracotomy when conventional transvenous implantation failed.

## Patients and Methods

From March 2014 to April 2015, 14 epicardial leads were implanted surgically at two different centers with the same surgical team. Written informed consent was obtained from all the patients. All patients who had cardiac heart failure functional class III or IV according to New York Heart Association (NYHA), dilated ischemic or non-ischemic cardiomyopathy dysfunction defined as LVEF <35% and a left bundle branch block (LBBB) (QRS duration >120 ms) were preselected by the cardiologists. Patient's demographic variables are listed in Table 1.

Electrocardiographic (ECG) QRS durations were automatically measured as the maximum of leads II and V6 were collected preoperatively and during the follow-up (after implantation, postoperative 2<sup>nd</sup>, 6<sup>th</sup> and 12<sup>th</sup> months) period to assess the difference in electrical dyssynchrony.

Left ventricular ejection fraction (LVEF) was measured using modified Simpson's method and left ventricle end-diastolic internal dimension (LVEDd) was measured using M-mode echocardiography, under two-dimensional guidance in the parasternal long-axis view. They were recorded preoperatively and during the follow-up period to analyze the effect of procedure.

## Statistical analysis

Mean and Standard Deviations (SD) were used for descriptive statistics; comparisons of quantitative variables were done using one-way ANOVA with tukey posthoc analysis. "P" value of <0.05 was considered statistically significant. All analysis was performed using SAS software V10.0 (SAS Institute Inc., Cary, NC).

**Table 2:** Reasons for failed transvenous lead implantation in all patients.

	Patients (n)	Patients (%)
Dissection of coronary sinus	2	14,3
Absence of suitable lateral coronary vein branches	6	42,9
Tortuous coronary sinus or target branches (failed cannulation)	6	42,9

## Epicardial lead implantation

The procedures were performed under general anesthesia with double endoluminal intubation. All procedures were performed electively. Patients had standard monitoring (ECG, pulse oximetry, caprometry, invasive arterial monitoring) and a Swan-Ganz catheter if needed. Patients were placed in supine position with left chest elevated 30-40°C. Following a left lateral mid-axillary mini-thoracotomy (approximately 7 cm to 8 cm) at the sight of the fourth intercostal space, the pericardium was opened anterior to the phrenic nerve and fixed with the traction-sutures while ensuring sufficient distance to expose the atrioventricular Groove and left ventricular posterobazale wall.

After mapping the LV to determine the optimal pacing location, a unipolar epicardial, steroid lead (Myodex 1084 T, Flexend 2 TM) was attached to the target area (posterobazale wall of the LV, between the left circumflex artery and obtuse marginal branch, below the left atrial appendage). After completing threshold measurements the lead was sutured in the selected position. The connector of the lead was brought through the third intercostal space and tunneled submuscular to the CRT-D device, in the pocket which was previously created in the left pectoral area. After completing the procedure pericardium was partially closed. Pleural chest tube was inserted operation was finished with standard wound closure.

## Results

Between March 2014 and April 2015, 14 patients (71% male) with a mean age of 73.1 ± 6.6 years underwent epicardial LV lead placement. Mean follow-up time was 16.5 ± 3.3 (12 to 23) months, mean intensive care unit stay was 24.7 ± 23.9 (8 to 102) hours and mean hospitalization time was 82.7 ± 46.4 (52 to 240) hours.

All patients had Left Bundle-Branch Block (LBBB) with mean (SD) QRS duration of 178.7 ± 18.1 ms (range 156-210 ms). All patients had previously undergone unsuccessful percutaneous lead placement. Reasons for failed transvenous lead implantation in all patients shared in Table 2. The main cause of failed percutaneous lead placement was anatomic in 14 patients (absence of suitable lateral coronary vein branches in 6 patients, tortuous coronary sinus in 6 patients).

All patients had advanced heart failure, with mean NYHA Class of 3.14 ± 0.3, LVEF 22.9 ± 2.3%.

All patients clinical, electrocardiographic and echocardiographic data before implantation and during follow-up is shown in Table 3.

NYHA, QRS interval and LVEF values of patients before implantation and during follow-up showed statistically significant difference (preprocedural vs. postprocedural 2<sup>nd</sup> month mean NYHA values 3.14 ± 0.3 vs. 1.7 ± 0.4, p<0.001, preprocedural vs. postprocedural mean QRS duration (ms) 178.7 ± 18.1 vs. 133,7 ± 4.7, p<0.001, preprocedural vs. postprocedural 2<sup>nd</sup> month mean LVEF (%) 22.9 ± 2.2 vs. 34 ± 2.8, p<0.001) whereas pacing threshold, left ventricle impedance and LVEDd values showed no statistically

**Table 3:** Clinical, electrocardiographic, and echocardiographic outcomes following epicardial lead placement.

	Patient (N)	Mean	Std	P value
NYHA Class				
Preprocedural	14	3,14	0,3	<0.001
Postprocedural 2 <sup>nd</sup> month	14	1,7	0,4	
Postprocedural 6 <sup>th</sup> month	14	1,6	0,4	
Postprocedural 12 <sup>th</sup> month	14	1,2	0,4	
QRS duration (ms)				
Preprocedural	14	178,7	18,1	<0.001
After implantation	14	133,7	4,7	
Postprocedural 2 <sup>nd</sup> month	14	133,6	5,6	
Postprocedural 6 <sup>th</sup> month	14	135,2	5,3	
Postprocedural 12 <sup>th</sup> month	14	136,8	4,9	
LVEF (%)				
Preprocedural	14	22,9	2,2	<0.001
Postprocedural 2 <sup>nd</sup> month	14	34	2,8	
Postprocedural 6 <sup>th</sup> month	14	38,5	3,5	
Postprocedural 12 <sup>th</sup> month	14	38,5	3,5	
Pacing Threshold (V)				
After implantation	14	0,65	0,21	ns
Postprocedural 2 <sup>nd</sup> month	14	0,67	0,20	
Postprocedural 6 <sup>th</sup> month	14	0,77	0,24	
Postprocedural 12 <sup>th</sup> month	14	0,79	0,34	
LV Impedance (Ω)				
After implantation	14	671,2	84,2	ns
Postprocedural 2 <sup>nd</sup> month	14	679,3	84,5	
Postprocedural 6 <sup>th</sup> month	14	699,7	83,3	
Postprocedural 12 <sup>th</sup> month	14	727,1	86,5	
LVEDd (mm)				
Preprocedural	14	69,5	2,2	ns
Postprocedural 2 <sup>nd</sup> month	14	68,5	2,2	
Postprocedural 6 <sup>th</sup> month	14	67,4	2,5	
Postprocedural 12 <sup>th</sup> month	14	66,2	2,9	

significant difference.

There were no operative deaths but one patient (7.1%) died at postoperative 18<sup>th</sup> month because of non-cardiac reason. One patient had pneumonia (7.1%) and one patient had bleeding (7.1%) (Not required re-exploration).

## Discussion

Cardiac Resynchronization Therapy (CRT) is proven adjuvant therapeutic option for selected patients with advanced chronic heart failure if pharmacological therapy alone is not sufficient. The results of several randomized clinical trials showed us CRT can prolong survival and improve quality of life [8].

Currently, transvenous placement of the LV lead via the coronary sinus is the first choice for CRT [9]. Success of this approach depends on coronary venous anatomy. The transveonus LV lead placement is unsuccessful in 4.3% to 7.5 % of patients [10].

Another study indicates that, approximately 25% of patients

have transvenous implantation failure (such as lead dislodgement, perforation, dissection and phrenic nerve or diaphragmatic stimulation) [11]. Furthermore, transvenous CRT lead implantation is associated with a 30% in-hospital complication rate (such as heart block, pericardial tamponade and effusion). In spite of all these negativities, transvenous approach seems to be the first line therapy for the CRT patients [12]. Alternative approaches were described as LV Endocardial Pacing (LVEP) and surgery (mini lateral thoracotomy, minimally invasive robotic-assisted thoracoscopic or video-assisted thoracoscopic approach) in cases if transvenous approach was not successful [13].

The Alternate Site Cardiac Re Synchronization (ALSNC) study reported that LVEP lead implant success rate was 89.4%, freedom from complications meeting the definition of primary endpoint was 82.2% at 6 months (95% CI, 75.6% to 88.8%). In this study 14 transient ischemic attacks (6.18%), 5 non-disabling strokes (3.8%) and 23 deaths (17.4%) (No death was from a primary endpoint complication) were observed. NYHA Class improvement reported in 59% of the patients and left ventricle end systolic volume reduction above 15% reported in 55% of the patients at sixth month control NYHA Class improvement was shown in all patients in our study [14].

Compared endovascular approach with epicardial approach and found that there were no significant differences between echocardiographic and clinical outcomes comparing a conventional approach versus surgical approach for CRT patients with heart failure Garikipati et al. [15].

Buiten et al. [16] indicated that epicardial LV lead implantation have an excellent long-term performance in durability and safety in CRT recipients. Likewise, Fang et al. [4] suggested that epicardial LV pacing for CRT in CHF is feasible and can bring satisfactory long-term results.

In our study, 14 patients underwent mini left lateral thoracotomy and implantation of an epicardial LV lead successfully and an optimal lead position was achieved in all patients. Apart from 2 patients (one patient had pneumonia, the other patient had minor bleeding) we did not observe any postprocedural complications (such as LV lead dislocation, high threshold, cardiac tamponade, phrenic nerve pacing) and mortality.

Recent studies indicated that epicardial lead implantation prolongs myocardial repolarisation duration (the potential mechanism remains unknown) and increases transmural dispersion of repolarisation, so that this pacing mode may have potential arrhythmogenic effects, and increase the risk of sudden cardiac death [17,18]. In our study none of the patients had serious ventricular arrhythmia during follow-up period. One patient died at postoperative 18<sup>th</sup> month because of non cardiac reasons.

## Conclusion

Transvenous lead implantation approach is the first line treatment choice for patients who need CRT implantation. If there is a presence of non suitable conditions for that approach, epicardial lead implantation should come to mind without enforcing transvenous approach.

## Limitations

The small number of patients and shortness of follow-up period

lessen the strength of our study. Also our study is not a comparative one. Despite these, we believe that our study add useful information to the literature about constituting an algorithm how to approach troublesome CRT patients.

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