

Ejection Fraction improvement in Left Ventricular only pacing vs Bi-Ventricular pacing in patients with heart failure.

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Abstract

Background: Left ventricular (LV) pacing with resynchronization therapy improves ventricular synchrony in patients with decreased LV function and Left Bundle Branch Block (LBBB). Objective: The goal of this study is to show that LV pacing is superior to BiVentricular (BiV) pacing in patients with ventricular dysfunction and LBBB. Methods: This is a retrospective study from 2 hospitals' registries in Lebanon. 121 patients with LVEF [?] 35%, a QRS [?]130msec and a LBBB pattern on full medical therapy were included in 2 groups: LV pacing and BiV pacing. All patients had echocardiograms before and after device implantation. The primary endpoint was the change in ejection fraction and the secondary endpoints were decrease in pulmonary artery pressure (PAPs), in LV end diastolic diameter (LVDD) and in LV end systolic diameter (LVSD). Statistical analysis was done with SPSS. Results: The study population was mostly males (69.4%) with ischemic cardiomyopathy 74 (61.2%) & a mean age of 67 years old. Fifty (41,3%) patients were programmed as LV pacing. A statistically significant improvement in EF was seen in the LV only 9.2% compared to BiV pacing 5.5%. Similarly, we noticed a significant decrease in the LVDD and LVSD in the LV pacing compared to the second group. There was a trend in favor of more PAPs improvement in the LV pacing that did not reach significance. Conclusion: This study demonstrates that LV pacing significantly improves EF and LV size compared to BiV pacing. A large multicenter trial is needed to confirm our findings.

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Abstract:

Background:

Left ventricular (LV) pacing with resynchronization therapy improves ventricular synchrony in patients with decreased LV function and Left Bundle Branch Block (LBBB). Ventricular activation in these cases may be obtained by recruiting the intrinsic AV conduction, over the right bundle branch that causes a multisite activation and a synchronized activity of the right ventricle and part of the septum. Fusion pacing between intrinsic AV conduction and LV capture initiate RV activation and compensate for LV electrical delay.

Objective:

The goal of this study is to show that LV pacing only is superior to BiVentricular (BiV) pacing in patients with left ventricular systolic dysfunction and LBBB.

Methods:

This is a retrospective study from 2 different hospitals' registries in Lebanon. 121 consecutive patients were identified between January 2014 and December 2019. Patients with LVEF $\geq$ 35%, a QRS $\geq$ 130msec and a LBBB pattern on full medical therapy were included in this study in 2 groups: LV pacing and BiV pacing. All patients had echocardiograms before and 3 to 6 months post device implantation. The primary endpoint was the change in ejection fraction and the secondary endpoints were decrease in pulmonary artery pressure in systole (PAPs), decrease in LV end diastolic diameter (LVDD) and decrease in LV end systolic diameter (LVSD). Statistical analysis was done with SPSS software & p-value <0.05 was considered significant.

Results:

The study population was mostly males (69.4%) (mean LVEF of 26.5%) with ischemic cardiomyopathy 74 (61.2%) and 47 (38.8%) patients with non-ischemic cardiomyopathy & a mean age of 67 years old. Fifty (41.3%) patients were programmed as LV only pacing. A statistically significant difference in improvement in EF was seen in the LV only arm 9.2% compared to BiV pacing arm 5.5%. Similarly, we noticed a significant decrease in the LVDD and LVSD in the LV pacing compared to the BiV pacing group. There was a trend in favor of more PAPs improvement in the LV pacing group that did not reach statistical significance.

Conclusion:

This study demonstrates that LV only pacing mode significantly improves EF and LV size compared to BiV pacing mode.

Introduction:

Ventricular dyssynchrony is a frequently observed feature in patients with left ventricular failure. Delays in ventricular conduction produces suboptimal filling, decrease in ventricular contractility, prolonged duration of mitral regurgitation (diastolic MR) and a paradoxical septal motion [1,2,3].

Left ventricular (LV) pacing with resynchronization therapy improves ventricular synchrony in patients with LBBB and poor LV function. Correcting electrical delay in left ventricle with a coronary sinus (CS) lead placement is especially important knowing that the right ventricular (RV) electrical activity may be normal in these cases. In BiV pacing, RV capture can cause RV dyssynchrony with a prolonged electrical activation. However, in LV pacing, impulses through the RBB to the Purkinjean fibers activates multiple RV sites and maintain RV synchrony "multisite activation". [5,6,7]. With isolated left univentricular pacing, fusion pacing between intrinsic AV conduction and LV capture initiate RV activation with or without pacing and in the same time compensate for LV electrical delay. In addition, decreasing RV pacing increases the longevity of the device and improves the current drain an advantage of LV pacing [8,9,10]. Moreover, studies on LV pacing mechanisms showed that a prestretching of the RV free wall and interventricular septum promote hypercontractility of both balanced by an LV free wall hypocontractility leading to a better RV contractility that appeared to enhance cardiac output. Improvement in output of the RV will sequentially increases the

LV output. However, the main issue is the variability of AV delay to provide an optimal fusion due to medications, disease status and daily activity. [8,11].

The aim of this study is to demonstrate that isolated LV pacing is as safe and better than other modes with a superior improvement in echocardiographic parameters.

Methods:

This is a Lebanese retrospective multicentric study. Patients were recruited from two different university hospitals between January 2014 till December 2019. Patients with LVEF [?] 35%, a QRS [?]130msec and a LBBB pattern on full medical therapy were included in this study in two groups: LV pacing and biventricular (BiV) pacing [Table1]. Echocardiogram before and 3 to 6 months after CRTD implantation were studied. Patients with complete heart block and permanent atrial fibrillation were excluded from this study. All local institutional review board approved the study and enrolled patients consented to the study.

Study design:

This study has been designed to test the hypothesis that LV pacing is as safe and more effective than BiV pacing. The primary composite endpoint, including a change in LVEF post CRT implantation. All patients included in this study underwent implantation of CRT-D devices with right atrial, right ventricular (RV) and LV leads.

The latter placed transvenously in a posterior, lateral or posterolateral branch of the coronary sinus. All Boston Scientific devices were programmed to LV only mode with AV delays programmed according to the SmartDelay™ optimization recommendation.

Other devices were programmed to BiVentricular pacing with AV delays programmed as per each company’s recommendation. All patients had echocardiograms before implantation and 3 to 6 months after the procedure. Measurements were performed according to EACVI and ASE recommendations [Figure1]

Primary endpoint:

The primary endpoint was a change in LVEF post device implantation.

Secondary endpoint:

The secondary endpoints included mitral regurgitation improvement, decrease in LVEDD, LVESD and left atrial dimension and improvement in hemodynamics with a decrease in systolic pulmonary pressures and amelioration in left ventricular end diastolic pressures.

Figure1: Study design

Inclusion criteria:
LVEF [?] 35%
QRS [?]130ms
LBBB
Patient on full guideline directed medical therapy (GMDT)
Exclusion criteria:
Complete heart block
Permanent atrial fibrillation

Table 1: Inclusion and exclusion criteria

Results:

Study population:

One hundred twenty-one patients were enrolled in this study. The study population is mostly males (69,4%)

with a mean age of 67 years old, mainly ischemic cardiomyopathy 74 (61,2%) and 47 (38,8%) patients with dilated cardiomyopathy. 50 (41,3%) patients were programmed as LV pacing and the rest 71(58,7%) as BIV pacing. They had a baseline mean LVEF of 26.5% with a mean QRS complex of 156 ms, typically with left bundle branch block (LBBB) morphology on full medical therapy. [Table 2]

Echocardiographic data and statistical analysis:

The statistical analysis was done with SPSS software for the evaluation of the hypothesis. T test was used for the analysis of the variables.

The baseline echocardiographic parameters in this population were as follow: a mean ejection fraction of (26,5%) with an LVEDD of (61,4mm) and an LVESD of (49,5mm). The hemodynamic findings preimplantation suggested a mean systolic pulmonary artery pressure of 47mmhg with 63% of patients with high left ventricular end diastolic pressure.

All patients had a dilated left atrium. 54,3% had a mild mitral regurgitation, 41,3 % moderate regurgitation and 4,4% with severe regurgitation. Three to six months of CRT pacing led to a reduction in LVEDD (57,9mm) and LVESD (47,47mm) and an improvement in LVEF (34,1%) in both arms.

Improvement was noticed in parameters post implantation in both programming options: a decrease in SPAP with a mean of 41,7mmhg, 51% of patients had normal LVEDP, 45,5% had a decrease in LA volume post implantation and 67% of patients had mild MR, 30,8% with a moderate regurgitation and 2,2% with severe MR [Table 3].

The echocardiographic findings in both groups separately are as follow: In the LV pacing arm (Group 1) the mean EF preimplantation was 26,9% vs 36,1% after implantation. On the other hand, for the BiV pacing (Group2); the mean EF preimplantation was 26,3% vs 31,8% after implantation. Data analysis showed a significant improvement in ejection fraction in the LV arm when comparing both groups with a P value of 0,043(P<0,05) and a 95% CI (confidence interval) with a mean amelioration of 9,2% vs 5,5% for group 2. Moreover, mean baseline LVEDD was 63,9mm with a reduction of the diastolic diameter post device implantation with a mean of 57,9mm for group1. For group 2, a mean baseline LVEDD of 60,4mm was noticed with a reduction of the diastolic diameter post device implantation with a mean of 59,2mm. A significant decrease in the LVEDD in the LV group with a P value of 0,007 and a 95% CI with a mean reduction of 6mm for the diastolic diameter of the ventricle. Furthermore, initial LVESD was 51,8mm vs 43,3mm after procedure for the LV arm. On the other hand, initial LVESD was 48,7 mm vs 48,7mm after procedure. Significant decrease in the LVSD was demonstrated in the LV pacing arm of 8,5mm with a P value of 0,03 and a 95% CI. For the pulmonary pressures, baseline was at 45,4 mmHg and months after 36,4 mmHg for group1 whereas for the 2nd group, the baseline pulmonary pressures were at 47,9 mmHg and months after 45,9 mmHg. Systolic pulmonary pressures improvement was noticed in both groups with a trend for the LV group and a decrease of 9mmHg vs 2mmHg for the other group. [Table 4] [cf supplemental material]

Descriptive data	n	%
Age	121	67
Sex		
Male	84	69,4
Female	37	30,6
Cardiomyopathy		
Ischemic	74	61,2
Dilated	47	38,8
Device programming		
LV pacing	50	41,3
BiV pacing	71	58,7

Table 2: Study descriptive data

	Pre-CRT-D	Post-CRT-D
EF	26,5%	34,1%
LVEDD	61,4mm	57,9mm
LVESD	49,5mm	47,47mm
PAPs	47 mmHg	41,7mmHg
LVEDP	Normal = 37% High=63%	Normal=51% High=48,8%
MR	Mild=54,3% Moderate=41,3% Severe=4,4%	Mild=67% Moderate=30,8% Severe=2,2%
LAVI	All dilated	45,5% decrease in indexed volume

Table3: Data describing parameters before and after CRTD implantation.

	Pre-CRT-D		Post-CRT-D		P value
	LV pacing	BiV pacing	LV pacing	BiV pacing	
LVEF	26,9%	26,3%	36,1%	31,8%	P=0,043
LVEDD	63,9mm	60,4mm	57,9mm	59,2mm	P=0,007
LVESD	51,8mm	48,7mm	43,3mm	48,7mm	P=0,03
PAPs	45,4mmHg	47,9mmHg	36,4mmHg	45,9mmHg	P=0,134

Table4: Statistical analysis revealing superiority of LV pacing vs BiV

Discussion:

In BiV pacing, RV capture can cause RV dyssynchrony with a prolonged electrical activation. However, in LV pacing, impulses through the RBB to the Purkinjean fibers activates multiple RV sites and maintain RV synchrony “multisite activation”. [5,8,11]

The very first studies showed that BiV pacing and LV pacing were similar with a trend for LV pacing due to optimal AV delay that provides fusion between the intrinsic RV conduction via a preserved RBB and LV pacing. Several other studies suggested that even when fusion is not reached LV pacing has benefits similar as BiV pacing as it was shown and confirmed in this study. [12,13]

Some studies elaborated a comparison between BiV and LV pacing. In BELIEVE randomized single blind study in 2006 with inclusion criteria similar to our study: NYHA II-IV, LBBB, sinus rhythm, QRS>130ms, ejection fraction≤ 35% and an LVEDD>=55mm a follow up for 12 months demonstrated an increase in ejection fraction of 5,2% in the LV group (9,2% in this study vs 5,5 in the BiV group) with a comparable safety profile with BiV pacing [14]. A pilot study, LOLA ROSE with 18 patients differentiating the two types of pacing showed no difference in peak Vo₂, 6MWD, QOL but a better NYHA in patients with Biv pacing [15]. In addition, The DECREASE-HF trial in 2007 studied 306 patients divided in 3 groups: simultaneous BiV, Sequential BiV and LV pacing. It showed during a follow up of 6 months, similar improvement in LVEDD, LVEDV, LVESD, SV, CO and EF in all groups with greater decrease in LVESD with simultaneous BIV pacing [16]. In 2010, 2 different studies compared BIV and LV pacing. B-LEFT-HF a prospective study involving 176 patients demonstrated no difference in primary endpoint, heart failure, composite score and adverse effects between the 2 groups demonstrated also in this study but with better hemodynamic and ejection fraction improvement [17]. On the other hand, Sedlacek et al, showed a trend in patients with BiV pacing [18]. Furthermore, a study in 2011, GREATER EARTH, involving 121 patients noticed an increase in more than 50% in exercise capacity in both groups with similar improvement in ejection fraction, LVESV, NYHA,6MWD and a similar incidence of adverse effects [19].

Moreover, in 2011, Thibault et al, a multicenter trial comparing the effect of LV and BIV pacing in 211 patients revealed that LV pacing was not superior to BiV pacing but non responders to BiV may respond to LV pacing [20]. In addition, this pacing strategy decrease costs by decreasing current drain, reduce implantation time and radiation exposure. A trial comparing the hemodynamic effect of BiV pacing VS LV pacing in patients that were first in BiV pacing mode then all set to LV pacing and assessed their echocardiographic findings. It showed a non-inferiority of LV pacing to BiV pacing with similar hemodynamic response. 21% who were non responders to BiV pacing responded better to LV pacing which is why it is logical that in our study LV pacing patients performed better than BiV [21]. Several benefits from LV pacing were noticed. Transition from BiV to LV pacing increased the longevity of the device with a decrease in costs, avoiding repeated procedures when RV lead were displaced or had high thresholds. In this study, we observed a better improvement in ejection fraction and hemodynamics in the LV pacing group vs the traditional biventricular pacing. This led us to think if it is appropriate to program patients to LV pacing in most cases. Further large and prospective studies need to be conducted to clear these issues.

Conclusion:

This study revealed that LV pacing was as safe and a better option than BIV pacing with better improvement in EF, LVEDD, LVESD and better hemodynamic parameters, thus, a better quality of life. Further studies are needed to shed the light on the possibility of programming most devices on an LV only pacing mode.

Conflict of interest:

The authors declare that there is no conflict of interest.

Funding:

The authors have not received any funding for this study.

Ethical approval:

All authors have been personally and actively involved in substantial work leading to the paper and will take public responsibility for its content. All local institutional review board approved the study and enrolled patients consented to the study.

Supplemental material:

T test on SPSS:

Group Statistics									
LV vs BIV		N	Mean	Std. Deviation	Std. Error Mean				
EF changes	LV	50	9.1800	9.95642	1.40805				
	BIV	71	5.5634	9.28398	1.10181				

Independent Samples Test									
Levene's Test for Equality of Variances				t-test for Equality of Means					
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference
EF changes	Equal variances assumed	.041	.840	2.048	119	.043	3.61662	1.76618	.11940 7.11384
	Equal variances not assumed			2.023	100.898	.046	3.61662	1.78790	.06987 7.16337

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Table4: Statistical analysis revealing superiority of LV pacing vs BiV

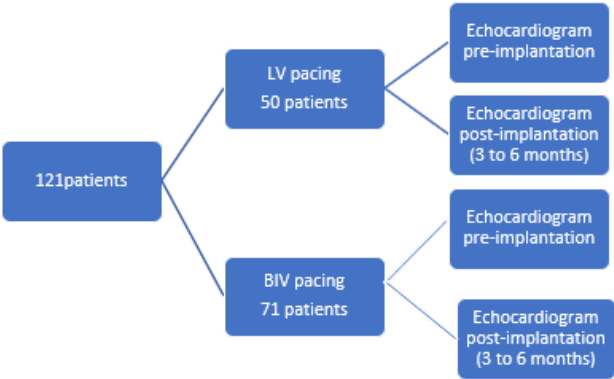


Figure1: Study design