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Lead related complications in quadripolar versus bipolar left ventricular leads

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ABSTRACT

Background: Quadripolar left ventricular (LV) leads are capable of pacing from four different electrodes which allows for easier and more stable intra-operative lead positioning with optimal pacing parameters. We therefore investigated the rate of combined intra-operative and post-operative LV lead related events in quadripolar vs. bipolar LV lead cardiac resynchronization therapy (CRT) recipients in the real world setting.

Methods: We retrospectively collected data for N = 1441 patients at our institution implanted with quadripolar (n = 292) or bipolar (n = 1149) LV leads from 2012 to 2014 and followed them to the primary end-point of composite lead outcome defined as intra-operative lead implant failure or post-operative lead dislodgement or deactivations.

Results: Patients implanted with a quadripolar lead were younger (70.6 ± 11.4 vs 72.5 ± 11.6, p = 0.014) and had higher incidence of diabetes (41.8% vs 32.8%, p = 0.004) compared to those with bipolar leads. All other baseline characteristics were comparable. Patients implanted with a quadripolar were significantly less likely to reach the primary endpoint in the first 12 months after LV lead implantation (Hazard Ratio 0.22, 95% Confidence Interval 0.08–0.60, p = 0.001). There were no differences between the two groups in rates of hospitalization for any cause or in mortality.

Conclusion: In this real world study, quadripolar LV leads have significantly lower rates of implantation failure and post-operative lead dislodgement or deactivation. These results have important clinical implications to CRT recipients.

1. Introduction

Congestive heart failure is a leading cause of morbidity and mortality with a 20%–30% death rate at 3 years [1,2,3]. Cardiac resynchronization therapy (CRT) is an effective adjunctive therapy for many heart failure patients [4,5]. CRT is achieved by pacing both the right (RV) and left (LV) ventricles with the LV lead usually placed in a branch of the coronary sinus through a transvenous approach [6]. Anatomical challenges occasionally result in failure of LV lead placement during the procedure or in lead dislodgement in the post-operative period, necessitating reoperation for repositioning [7,8,9]. The major reasons for reoperation are LV lead dislodgement with loss of capture, phrenic nerve stimulation (PNS), and increased LV pacing thresholds without obvious lead dislodgement [9]. Recently, approved quadripolar LV leads have provided more options for LV pacing, giving operators more choices for LV lead positioning with less compromise in lead stability. It remains however unclear whether these technological advances translate into better procedural or clinical outcomes for CRT recipients. We therefore sought to investigate differences in the rates of combined intra-operative and post-operative LV lead related complications in patients receiving quadripolar versus bipolar LV leads in real-world clinical practice and examine potential differences in longer term clinical outcomes.

2. Methods

This is a single center, observational study comparing differences in patient outcomes after CRT based on the type of the

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implanted LV lead LV (Quadripolar vs. Bipolar). The study was approved by the Institutional Review Board of the University of Pittsburgh. All patients who had an attempt at CRT defibrillator (CRT-D) or pacemaker (CRT-P) device implantation at the hospitals of the University of Pittsburgh Medical Center (UPMC) between 2011 and 2014 were included in this study. Both *de novo* CRT implantations and upgrades from other devices to CRT were included. Baseline demographic and clinical variables including pre-procedural assessment of left ventricular ejection fraction (EF) were collected. Institutional reports to the National Cardiovascular Data Registry - ICD registry together with the UPMC electronic health records (EHR) were used as sources of information.

The index procedure was the *de novo* or upgrade CRT procedure. Operative notes were reviewed to identify patients with failed attempts at LV lead placement. EHR were reviewed to capture all instances of procedural or LV lead related complications. Outcomes including hospitalization for any reason (device-related complications, heart failure, and arrhythmia) were abstracted from the EHR. Phrenic nerve stimulation (PNS) during follow-up visits was also recorded. Mortality data was obtained from the electronic medical records, including scanned death certificates, as well as from the Social Security Death Index records through October 2015.

The choice of the model and manufacturer of CRT devices and LV leads was left to the discretion of the implanting physician. Quadripolar LV leads included the Food and Drug Administration approved St. Jude Medical (Sylmar, CA) 'Quartet' lead and the Medtronic (Minneapolis, MN) 'Attain Performa' family of leads.

The implantation procedure was performed by electrophysiologists who were experienced in performing CRT procedures. All operators had no less than 3 years of experience in implanting LV leads from different manufacturers. The site of LV pacing was chosen by the implanting physician based on lead stability, the absence of PNS, and favorable pacing parameters. Device programming was at the discretion of the implanting physician. A failed attempt at LV lead placement was defined as abandoned LV lead implantation during the index procedure.

Patients were followed to the primary composite end-point of LV lead implant failure, dislodgment, or LV pacing deactivation for PNS in the first 12 months after the index procedure. Secondary outcomes include all-cause hospitalizations, device-related hospitalizations, hospitalization for arrhythmia, hospitalization for heart failure, and all-cause mortality. Hospitalizations were defined as at least one overnight stay in the hospital under admission or observation status. Patients were followed by the device clinic at UPMC. All patients presented to the clinic 2 weeks after the index procedure for a surgical wound check at the site of device implantation. Their follow-up thereafter consisted of clinic visits every 6 months or clinic visits once a year with scheduled home monitoring downloads every 3 months.

Baseline characteristics were presented as mean ± standard deviation for continuous variables and as n (%) for categorical variables. Differences between patients receiving quadripolar vs. bipolar LV leads were compared using the Student's *t*-test and chi-squared tests, respectively. Incidence of time-to-event outcomes was analyzed using Kaplan-Meier analyses and compared between quadripolar and bipolar LV lead recipients using the log-rank test. Statistical analyses were performed using SAS version 9.4 (SAS Institute, Cary NC).

3. Results

A total of 1441 patients (292 quadripolar and 1149 bipolar) were implanted with a CRT device between January 2011 to December 2014. They were followed-up for a mean of 609 ± 480 days. Of the overall cohort, 1220 (85%) patients had at lead 1 year of follow-up. Table 1 shows the baseline characteristics of the overall cohort and of the quadripolar vs. bipolar groups. Compared to patients receiving a bipolar LV lead, patients receiving quadripolar leads were younger (70.6 ± 11.4 vs. 72.5 ± 11.6, p = 0.01) and had more Diabetes mellitus (42% versus 33%, p = 0.004). All other baseline characteristics were comparable between the two groups. Among the implanted quadripolar LV leads, 224 were from St. Jude Medical (Sylmar, CA) and 68 from Medtronic (Minneapolis, MN). There were no differences in LV lead complications or patients outcomes by lead model or manufacturer.

There were a total of 28 failed attempts at LV lead placement [1 (0.3%) in the quadripolar group vs. 27 (2.3%) in the bipolar group, p = 0.029]. There were no instances of switching from a quadripolar to a bipolar LV lead or *vice versa* during the index procedure. Over 12 months of follow-up, the composite endpoint of LV lead related complications occurred significantly less in the quadripolar compared to the bipolar group [8 (2.7%) compared to 78 (6.8%), p = 0.009]. The individual components of the composite end point of LV lead related complications and their rates between the two

Table 1
Pre-Implant Characteristics of N = 1441 patients (2011–2014).

	Overall Cohort	Bipolar	Quadripolar	P-Value
Number of Patients	1441	1149	292	
Age	72.1 ± 11.6	72.5 ± 11.6	70.6 ± 11.4	0.014
BMI	29.5 ± 9.9	29.5 ± 10.6	29.5 ± 6.3	0.932
Diabetes Mellitus	499 (34.6%)	377 (32.8%)	122 (41.8%)	0.004
Hypertension	1059 (73.5%)	840 (73.1%)	219 (75.0%)	0.569
Prior myocardial Infarction	667 (46.3%)	545 (47.4%)	122 (41.8%)	0.076
Prior PCI	355 (24.6%)	285 (24.8%)	70 (24.0%)	0.750
Prior CABG	441 (30.6%)	357 (31.1%)	84 (28.8%)	0.429
Prior Heart Failure	1266 (87.9%)	1011 (88.0%)	255 (87.3%)	0.669
Prior Heart Failure Hosp.	492 (34.1%)	387 (33.7%)	105 (36.0%)	0.084
NYHA Class				0.178
1	84 (5.8%)	70 (6.1%)	14 (4.8%)	
2	251 (17.4%)	189 (16.4%)	62 (21.2%)	
3	791 (54.9%)	639 (55.6%)	152 (52.1%)	
4	47 (3.3%)	39 (3.4%)	8 (2.7%)	
Atrial Fibrillation	756 (52.5%)	616 (53.6%)	140 (47.9%)	0.073
QRS Width	150 ± 31.4	150 ± 31.4	150 ± 31.4	0.957
Creatinine	1.32 ± 0.88	1.30 ± 0.85	1.37 ± 0.99	0.224
Pre-Implant LVEF	28.4 ± 11.6	28.4 ± 11.6	28.1 ± 11.3	0.652
CRT Upgrade Procedure	572 (39.7%)	476 (41.4%)	96 (32.8%)	<0.001
Total Follow Up Time (Days)	609 ± 480	698 ± 490	256 ± 189	<0.001

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