

# Acute and mid-term outcomes of transvenous implant of a new left ventricular quadripolar lead versus bipolar leads for cardiac resynchronization therapy: Results from a single-center prospective database

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## Abstract

**Background:** *The purpose of this study was to evaluate the feasibility of the use of a quadripolar left ventricular (LV) lead for cardiac resynchronization therapy and to compare its acute and mid-term outcomes with those obtained with bipolar leads. Cardiac resynchronization exhibits a high incidence of problems involving the LV lead when conventional leads are used, and these problems may be minimized by using multipolar leads.*

**Methods:** *We gathered clinical, implant, and follow-up data at 3 and 9 months from 21 consecutive patients in whom a quadripolar (Group Q) or bipolar (Group B) lead was used for a biventricular defibrillator implant.*

**Results:** *The leads were successfully implanted in all of the patients. In Group B, more than one lead was used in 20% ( $p = 0.048$ ) of cases. There were no clinical differences or differences in the implant parameters between the two groups except for the radiation dose, which was greater in group B ( $p = 0.035$ ). The incidence of problems related to the LV lead during follow-up was higher in group B, but the difference was not significant (42.9% vs. 23.8%,  $p = 0.326$ ). The use of more than one LV lead was the only variable that was significantly associated with lead-related problems during follow-up ( $p = 0.03$ ; OR = 10.8; 95% CI 1.07–108.61).*

**Conclusions:** *The quadripolar lead was associated with excellent implantation success rates and mid-term performance. The multi-programmability capabilities of quadripolar leads facilitated the achievement of implant goals and helped to reduce problems during the implant and follow-up. (Cardiol J 2012; 19, 5: 470–478)*

**Key words:** cardiac resynchronization, left ventricular lead, heart failure, cardiac pacing, coronary sinus

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## Introduction

Cardiac resynchronization therapy (CRT) is not free of problems and complications that may limit its benefits. Some patients do not respond to the therapy, and other potential problems include phrenic stimulation, the absence of an adequate capture threshold, lead dislocations (especially the left ventricular [LV]), and in general, a higher rate of events related to the device compared with patients who receive cardiac defibrillator (ICD) implants without CRT [1–3]. To overcome many of these difficulties, new technical advances had been developed in the last few years but despite these developments, the leads cannot be properly positioned in some patients [4], and non-percutaneous surgical implantation is used whenever possible.

One of the most significant innovations has been the development of a quadripolar LV lead (Quartet, model 1458Q, St. Jude Medical, Sylmar, CA, USA) with a maximum body diameter of 4.7 F, composed of a distal electrode (D1) and three rings (M2, M3 and P4) that are capable of applying pacing from the four electrodes. This capability and the lead's right ventricle (RV) coil ability to act as an anode allow up to 10 bipolar pacing configurations (6 purely bipolar and 4 extended bipolar) to be applied with this quadripolar lead (Fig. 1). The main goal of this multi-programmability is to decrease the need for surgical revisions and prevent the loss of CRT due to threshold or phrenic stimulation problems that cannot be non-invasively corrected [5–8]. The use of these leads could overcome the difficulties of successful implantation with conventional leads in some patients [9]. This observa-

tional study involves an analysis of the technical, acute to mid-term results in a center utilizing the aforementioned lead and a global comparison of these results with those obtained in a group of patients who received conventional bipolar lead implants within the same period of time.

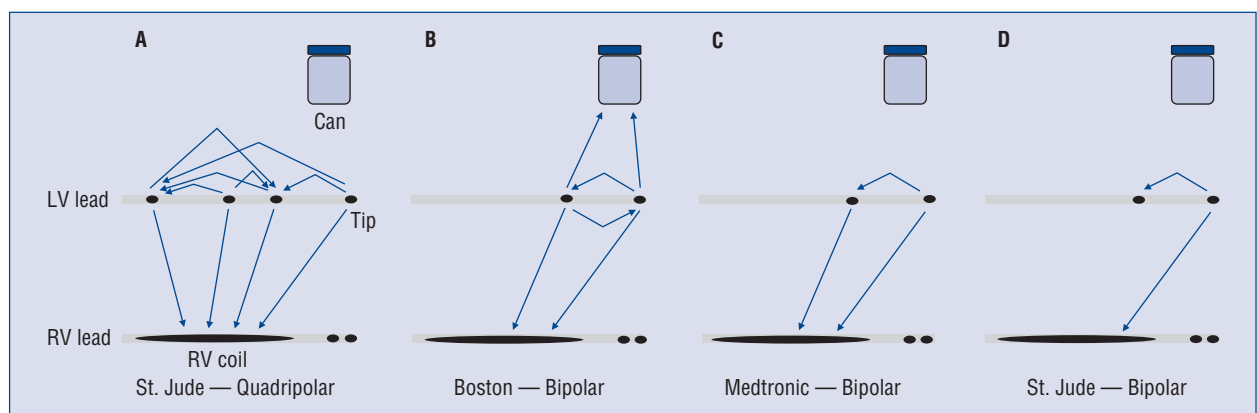
## Methods

### Patients and left ventricular lead

Consecutive patients with an indication of standard CRT associated with an ICD, in whom a coronary sinus (CS) lead implant was attempted for the first time, were included in this study. All of the patients gave informed consent. LV quadripolar leads were used in half of the subjects (Group Q), and conventional bipolar leads from a variety of manufacturers were used in the other half (Group B). The lead types were selected prior to implantation and independently of the patient characteristics. In both groups, the distal electrode of the ventricular lead was called P1, and the ring was called M2. For the quadripolar lead, the other rings were named M3 and M4, from tip to proximal.

### Device implant

At the time of implantation, we gathered demographical and clinical data about the patients, their type of indication (primary or secondary), QRS width, baseline rhythm, cardiovascular risk factors, cardiovascular medications, and New York Heart Association (NYHA) functional class. We also obtained electronic data related to the implanted device and the LV leads including the threshold, the R wave, the final impedance in the programmed



**Figure 1.** Outline of the different programmable left ventricle (LV) pacing vectors in the studied patients for each lead type and device manufacturer. For each vector (shown with a blue arrow), the tip and origin of the arrow identify the anode and cathode, respectively; RV — right ventricle.

configuration, the final position of the lead, the number of leads used to achieve the implant goal, the total radioscopy time and dose of the implant, and whether the implant was successful in the first approached vein. In all cases, access for positioning the LV lead was gained by subclavian venous puncture, and a CS angiography was performed to understand the venous anatomy and to visualize the target vein. The final position of the lead and the final pacing configuration chosen from the programmable options available for each LV lead model were determined in each case by the physician conducting the implant, with the goals of avoiding purely anterior positions and finding an equilibrium between the programmed output current and an acceptable threshold in the absence of phrenic stimulation. The programmed output targeted a value at least 1.5 times the obtained capture threshold to maintain a safety margin between the pacing output and the pacing threshold value +1 V [10]. All of the patients received prior placement of an active fixation defibrillation lead in the RV and, in patients who did not have chronic atrial fibrillation, an active fixation lead in the right atrium. The leads were connected to an appropriate and compatible generator produced by the same manufacturer as the leads.

### Follow-up and events

The patients were discharged the day after they received implants in the absence of complications. Before the patients were discharged, the auriculoventricular and interventricular intervals were optimized by echocardiography and posteroanterior and lateral chest X-rays. The patients were examined at 3 and 9 months after receiving the implants and when clinical events required an earlier visit or hospitalization for cardiological reasons. At each visit, we recorded clinical data and data related to the threshold capture and impedance of the LV lead pacing, the presence of clinical phrenic stimulation during the analyzed periods, the radiological positions of the leads, and the need for surgical revision or setting changes.

### Definitions

**Success of LV lead implant:** Lead placed in a stable position, with a threshold lower than 3 V, and phrenic stimulation limited to a voltage 1.5 times that of the capture threshold's value.

**"LV lead problems":** The first of any of the following events before discharge, between discharge and the 3-month visit, or between the 3-month visit and the 9-month visit: macro-dislodgement

of the LV lead, resulting in the lack of adequate capture parameters; intermittent or continuous phrenic stimulation reported by the patient; lack of LV capture due to a threshold increase at the follow-up in the absence of LV lead dislodgement.

### Statistical analysis

Data were analyzed with the SPSS program (version 15.0, SPSS Inc., Chicago, Ill, USA). The discrete variables were expressed as absolute values and percentages, and the continuous variables were expressed as means  $\pm$  standard deviation. The categorical variables were compared using Fisher's test (for  $2 \times 2$  tables) or the  $\chi^2$  test, while the continuous variables were compared with Student's t test. P-values less than 0.05 were considered to be statistically significant.

## Results

### Baseline characteristics of patients

We included 42 consecutive patients in this study (mean age  $65.6 \pm 9.9$  years, 69% male), each of whom received an ICD implant with CRT. Half of the patients ( $n = 21$ ) received a quadripolar lead for LV pacing (Group Q), and the other half ( $n = 21$ ) received a bipolar lead (Group B). The general characteristics of the patients are presented in Table 1. The majority of the patients (39) were receiving their first device implant. The patients presented with severely reduced LV ejection fractions (LVEF) ( $22.1 \pm 5.8\%$ ), the NYHA functional class of each patient was greater than I, and 83% of the included patients were in sinus rhythm.

We did not observe statistically significant differences between the baseline characteristics of the Group Q and Group B patients, with the exception that more of the patients in Group B (Table 1) used diuretics.

### Device implantation

Successful percutaneous implantation of the lead into the CS was achieved in all of the patients from both groups (100%). In the majority of the cases (34 patients [81%], 18 in Group Q [85.7%] and 16 in Group B [76.2%],  $p = 0.697$ ), implantation was possible on the first attempted branch of the CS. In Group B, 4 families of bipolar leads were used (9 models) from three manufacturers. Table 2 presents the general data about these bipolar leads. During the implant procedure, a single quadripolar lead per patient was used in Group Q, while a total of 26 leads were used in 21 patients in Group B (Table 2). Two leads were required in 5 patients to

**Table 1.** General characteristics of the patients studied.

	Total (n = 42)	Group Q (n = 21)	Group B (n = 21)	P
Age [years]	65.6 ± 9.9	63.90 ± 9.7	67.33 ± 10.04	0.268
Males	29 (69)	14 (66.7)	15 (71.4)	1.000
Renal insufficiency	7 (16.7)	3 (14.3)	4 (19%)	1.000
Medications:				
Beta-blockers	37 (88.1)	19 (90.5)	18 (85.7)	1.000
ACE-I	28 (66.7)	13 (61.9)	15 (71.4)	0.744
ARB	11 (26.2)	7 (33.3)	4 (19.0)	0.484
Diuretics	31 (73.8)	12 (57.1)	19 (90.5)	0.032
Type of Implant:				0.599
First implant	39 (92.9)	20 (95.2)	19 (90.5)	
Upgrading from pacemaker	2 (4.8)	1 (4.8)	1 (4.8)	
Upgrading from defibrillator	1 (2.4)	0 (0)	1 (4.8)	
Cardiomyopathy:				0.758
Ischemic dilated cardiomyopathy	20 (47.6)	9 (42.9)	11 (52.4)	
Non-ischemic dilated cardiomyopathy	22 (52.4)	12 (57.1)	10 (47.6)	
Indication:				1.000
Primary prevention	33 (78.6)	17 (81)	16 (76.2)	
Secondary prevention	9 (21.4)	4 (19)	5 (23.8)	
LVEF [%]	22.1 ± 5.8	22.48 ± 6.1	21.7 ± 5.5	0.695
NYHA functional class at time of implant				0.248
I	0 (0)	0 (0)	0 (0)	
II	13 (31)	9 (42.9)	4 (19)	
III	24 (57.1)	10 (47.6)	14 (66.7)	
IV	5 (11.9)	2 (9.5)	3 (14.3)	
Type of QRS				0.343
LBBB	28 (66.7)	15 (71.4)	13 (61.9)	
Paced	2 (4.8)	0 (0)	2 (9.5)	
IVCD	12 (28.6)	6 (28.6)	6 (28.6)	
Width of QRS in ms	153 ± 19	151 ± 21	156 ± 17	0.373
Baseline rhythm:				1.000
Sinus rhythm	35 (83.3)	17 (81)	18 (85.7)	
Atrial fibrillation	7 (16.7)	4 (19)	3 (14.3)	

ACE-I — angiotensin converting enzyme inhibitors; ARB — angiotensin II receptor blockers; LVEF — left ventricular ejection fraction; NYHA — New York Heart Association; LBBB — left bundle branch block; IVCD — intraventricular conduction disorder; results expressed as n (%) (discrete variables) and means ± standard deviation (continuous variables)

achieve the implant goal ( $p = 0.048$ ) (Table 3) due to a lack of stability (2 patients), an inability to access the venous branch (1 patient), or because of inappropriate acute threshold capture and phrenic stimulation parameters (2 patients).

No significant differences in the final positions (tips) of the LV leads, the threshold, the R wave, the impedance at the final position, or the configuration of the programmed pacing vector of the two groups were observed (Table 3). In Group B, patients received significantly higher radiation doses ( $p = 0.035$ ) and higher total radioscopy times ( $p = 0.054$ ). The configuration of the LV pacing

vector varied widely due to the diversity of options for each lead and device, especially in Group Q (Fig. 1). Overall, we were able to program a total of 13 configurations, but only 3 (P1-M2, P1-RV coil, and M2-RV coil) were available in both patient groups (Fig. 1, Table 3). In 7 patients in Group Q (33.3%), non-programmable final configurations were chosen using bipolar leads. A final non-programmable LV pacing configuration was chosen for 1 patient in Group B using a quadripolar lead. Only 2 acute complications were observed, both in Group Q ( $p = 0.488$ ). One patient with acute pulmonary edema presented with dislocation of the LV lead

**Table 2.** Left ventricular lead models used in the two groups.

	Manufacturer	Lead family	Lead model	Maximum diameter	No. of leads
<b>Group Q</b>					<b>21</b>
	St. Jude Medical	Quartet	1458Q	5.1 F	21
<b>Group B</b>					<b>26</b>
	Medtronic	Attain Ability	4196	4.6 F	5
	Medtronic	Attain Ability	4296	5.3 F	1
	St. Jude Medical	Quickflex	1156T	5.6 F	3
	St. Jude Medical	Quickflex	1258T	4.3 F	2
	Boston Scientific	Acuity	4554	5.4 F	2
	Boston Scientific	Acuity	4555	5.4 F	10
	Boston Scientific	Easytrack-2	4543	5.7	2
	Boston Scientific	Easytrack-3	4548	6	1

Group Q — group with quadripolar lead; Group B — group with bipolar lead

**Table 3.** Comparison of implant parameters of the two groups.

	Total (n = 42)	Group Q (n = 21)	Group B (n = 21)	P
Position of the LV lead tip:				0.440
Basal-lateral	5 (11.9)	1 (4.8)	4 (19.0)	
Medio-lateral	20 (47.6)	12 (57.1)	8 (38.1)	
Apical-lateral	4 (9.5)	3 (14.3)	1 (4.8)	
Basal-posterior	1 (2.4)	1 (4.8)	0 (0)	
Medio-posterior	4 (9.5)	2 (9.5)	2 (9.5)	
Apical-posterior	2 (4.8)	0 (0)	2 (9.5)	
Basal-anterolateral	3 (7.1)	1 (4.8)	2 (9.5)	
Medio-anterolateral	1 (2.4)	0 (0)	1 (4.8)	
Apical-anterolateral	2 (4.8)	1 (4.8)	1 (4.8)	
LV threshold [V]	1.08 ± 0.56	1.03 ± 0.56	1.14 ± 0.56	0.541
Pacing impedance [Ohm]	836 ± 281	799 ± 239	874 ± 318	0.391
LV R wave [mV]	14.3 ± 4.8	14.1 ± 4.9	14.6 ± 4.9	0.754
Radioscopy dose [cGy/cm <sup>2</sup> ]	4367 ± 3608	3191 ± 2357	5544 ± 4269	0.035
Duration of radioscopy [min]	32.2 ± 20	26 ± 11	38.3 ± 26	0.054
Programmed LV configuration:				
P1-M2	16 (38.1)	5 (23.8)	11 (52.4)	
P1-M4	0 (0)	0 (0)	—	
M4-M2	0 (0)	0 (0)	—	
M3-M2	3 (7.1)	3 (14.3)	—	
M2-M4	0 (0)	0 (0)	—	
M3-M4	0 (0)	0 (0)	—	
P1-RV coil	11 (26.2)	2 (9.5)	9 (42.8)	
M2-RV coil	7 (16.7)	7 (33.3)	0 (0)	
M3-RV coil	1 (2.4)	1 (4.8)	—	
M4-RV coil	3 (7.1)	3 (14.3)	—	
M2-P1	0 (0)	—	0 (0)	
P1-Can	1 (2.4)	—	1 (4.8)	
M2-Can	0 (0)	—	0 (0)	

LV — left ventricle; RV — right ventricle; Group Q — group with quadripolar lead; Group B — group with bipolar lead; results expressed as n (%) (for discrete variables) and mean ± standard deviation(continuous variables)

**Table 4.** Comparison of variables related to left ventricular pacing during follow-up in the two groups.

	Total (n = 42)	Group Q (n = 21)	Group B (n = 21)	P
LV threshold at 3 months [V]	1 ± 0.5	1.04 ± 0.6	0.97 ± 0.3	0.647
LV impedance at 3 months [Ohm]	754 ± 213	796 ± 220	712 ± 202	0.204
LV threshold at 9 months [V]	0.99 ± 0.3	1.04 ± 0.3	0.94 ± 0.3	0.276
LV impedance at 9 months [Ohm]	722 ± 218	785 ± 218	662 ± 206	0.080
Phrenic stimulation	10 (23.8)	3 (14.3)	7 (33.3)	0.277
Phrenic stimulation before 3 months	6 (14.3)	1 (4.8)	5 (23.8)	0.184
Phrenic stimulation between 3 and 9 months	8 (20.5)	2 (10.5)	6 (30)	0.235
Leads macro-dislodgement	3 (7.1)	1 (4.8)	2 (9.5)	1.000
Loss of capture	2 (4.8)	2 (9.5)	0 (0)	0.488
“LV lead problems”	14 (33)	5 (23.8%)	9 (42.9)	0.326
Causes of “LV lead problems”:	<b>N = 14</b>			0.115
Phrenic stimulation	9 (64.3%)	2 (40%)	7 (77.8)	
Macro-dislodgement	3 (21.4)	1 (20)	2 (22.2)	
Loss of capture	2 (14.3)	2 (40)	0 (0)	
Time of “LV lead problems”:				0.780
Before discharge	2 (14.3)	1 (20)	1 (11.1)	
Between discharge and 3 months	10 (71.4)	3 (60)	7 (77.8)	
Between 3 and 9 months	2 (14.3)	1 (20)	1 (11.1)	

LV — left ventricle; Group Q — group with quadripolar lead; Group B — group with bipolar lead; results expressed as n (%) (for discrete variables) and mean ± standard deviation (continuous variables)

during tests with the analyzer, which was resolved with medical treatment and repositioning of the lead without further incidents. Another patient presented with severe symptomatic hypotension without evidence of mechanical complications, and the complication was resolved with vasoactive drugs and without further incidents.

### Follow-up data

There were 4 deaths, all of which occurred between the 3-month and 9-month follow-up visits. One death was due to refractory heart failure, another occurred during major peripheral artery surgery on a patient in Group Q, and 2 were related to cardiogenic shock in patients in Group B. The number of responders was the same in both groups (81%, 17 of 21 patients per group). The electrical parameters of the LV leads (pacing threshold and impedance) remained stable in both groups from the time of implantation to the 2 subsequent visits (Table 4).

Clinical phrenic stimulation during follow-up occurred more frequently in Group B (Table 4). Of the 10 patients exhibiting phrenic stimulation, only 3 were from Group Q ( $p = 0.27$ ). Phrenic stimulation in these 10 patients occurred after discharge. In 4 of the patients (all from group B), phrenic stimulation presented in both the time period between discharge and the 3-month follow-up visit and be-

tween the 3-month and the 9-month follow-up visits, even though it had been corrected in each of these patients during the previous visit. In 1 patient, phrenic stimulation was corrected by reducing the output and in another, by changing the LV pacing configuration. In 2 of the 3 patients in which output reduction was the only option, the safety margin of the threshold +1 V was reprogrammed to prevent phrenic stimulation (Cases 9 and 11, Table 5), and in one of them (Case 11, Table 5), none of the LV capture and phrenic stimulation thresholds in any of the possible configurations prevented phrenic stimulation without losing capture by the 9-month visit. This patient was programmed without pacing using the LV lead and underwent surgical revision and lead repositioning.

The frequencies of loss of capture without and with macro-dislodgement of the LV lead in the two groups were not significantly different (Table 4).

We observed a higher frequency of “LV lead problems” in Group B, but the difference was not statistically significant ( $p = 0.326$ ). “LV lead problems” occurred in one third of the patients (14 patients [33.3%], 9 from Group B and 5 from Group Q), and presented most frequently between discharge and the 3-month follow-up visit. The most frequent cause was phrenic stimulation (in 9 patients), followed by macro-dislodgement of the LV lead (in

**Table 5.** Details of the patients with “LV lead problems” during follow-up.

Case	Group	No. of LV lead used	NYHA implant	LVEF (%)	Threshold at implant [V], at 0.5 ms	Impedance at implant [Ohm]	Programmed LV configuration	Radioscopy dose	Problem cause	Action taken
1	Q	1	III	28	1	1070	M3-RV coil	14615	Phrenic stimulation	Change of LV pacing configuration to M4-RV coil
2	Q	1	IV	25	0.5	1025	P1-M2	2814	Macro-dislodgement	Surgical revision
3	Q	1	III	20	2.3	340	M2-RV coil	1616	Loss of capture	Change of LV pacing configuration to M4-RV coil
4	Q	1	II	30	1.5	710	P1-RV coil	2619	Loss of capture	Change of LV pacing configuration to M2-RV coil
5	Q	1	II	15	0.7	850	M2-RV coil	2069	Phrenic stimulation	Adjustment of pacing output
6	B	1	III	20	1.7	494	P1-RV coil	8091	Phrenic stimulation	Adjustment of pacing output
7	B	1	III	30	1.3	959	P1-Can	3600	Macro-dislodgement	Surgical revision
8	B	2	III	20	0.6	648	P1-RV coil	18215	Phrenic stimulation	Adjustment of pacing output
9	B	2	III	20	1.1	1418	P1-M2	15885	Phrenic stimulation	Adjustment of pacing output
10	B	2	IV	20	0.2	405	P1-RV coil	9629	Phrenic stimulation	Adjustment of pacing output
11	B	1	III	25	0.5	1348	P1-M2	2772	Phrenic stimulation	Adjustment of pacing output
12	B	1	III	20	2.4	1138	P1-M2	12792	Phrenic stimulation	Change of LV pacing configuration to M2-RV coil
13	B	2	III	15	1.5	1001	P1-RV coil	6705	Macro-dislodgement	Surgical revision
14	B	1	III	15	0.8	1060	P1-M2	9435	Phrenic stimulation	Adjustment of pacing output

LV — left ventricle; LVEF — left ventricular ejection fraction; NYHA — New York Heart Association; RV — right ventricle

3 patients), but there were no statistically significant differences between Groups Q and B with respect to the cause or the time of event occurrence (Table 4). The only variable significantly associated with the occurrence of “LV lead problem” events was the use of more than one LV lead during implantation to achieve the target goal ( $p = 0.03$ ; OR = 10.8; 95% CI 1.07–108.61). The use of a bipolar LV lead vs. a quadripolar lead, despite the presence of more events in Group B (9 vs. 5), did not produce a statistically significant difference. The data from patients presenting with “LV lead problem” events are summarized in Table 5.

Regarding post-implant complications not related to the LV lead, there were 3 cases of pocket hematoma that required surgical drainage prior to discharge (2 in Group B and 1 in Group Q), 1 case of infection in Group Q that was detected during the 9-month follow-up visit and required complete extraction of the system, and a subacute perforation of the RV by the defibrillation lead in Group Q, which required surgical revision prior to discharge.

## Discussion

### Main findings

The main findings of this study include: (a) CRT using a quadripolar Quartet 1458Q lead for LV pacing was associated with an excellent implant success rate, equal to that observed using conventional leads; (b) in this series, the frequency of problems related to this type of lead was less than that observed with bipolar leads, although the difference was not statistically significant; (c) the use of a single quadripolar lead was sufficient to achieve the acute objectives of the implant, while more than one lead was frequently required when conventional leads were used.

### Previous studies

Outcomes using this quadripolar lead have only been reported in a few previous studies, two from the same group (initially with 28 patients [7] and later with 40 [8]), and another from multiple centers, including one where 71 patients were analyzed prospectively [8]. A fourth study represents the only other comparison of a group of 23 patients with bipolar leads to a group of 22 patients with quadripolar leads but included a follow-up period of only 3 months [5]. All of these prior studies reported a highly elevated implant success rate for the quadripolar leads, which varied between 95% [8] and 100% [5] of cases. The success rate of quadripolar lead implantation in the first selected vein in this

work was greater than that reported in a previous study (85.7% vs. 78% [8]), which could be related to the larger number of patients with history of a previous device in this study (32% vs. 4.8%); some of these previous implantations included a failed conventional lead implant attempt.

### Programming flexibility

The measured stability of the electrical parameters after quadripolar lead implants presented in this study agrees with the observations of previous studies, and our study includes a longer follow-up time. This stability and the programming flexibility of quadripolar leads help to minimize capture and phrenic stimulation problems during follow-up (present in over 20% of patients with bipolar leads [3]) because it is possible to select configurations that include safety margins between capture and phrenic stimulation. The majority of the problems observed during the follow-up periods of previous studies were corrected without invasive interventions [5, 6, 8], as occurred in our patients. The multi-programmability of the quadripolar lead facilitates the observed increased ease of lead placement, which is indirectly measured by the lower radiation doses and times (data from our series) and the duration of lead implantation [5]. The use of a quadripolar lead was able to achieve the implant goals in certain patients in whom conventional leads were insufficient [9].

The quadripolar lead allows us to position the tip more apically, which facilitates its stability and permits pacing from more proximal regions, minimizing phrenic stimulation and possibly improving the clinical results by avoiding pacing in more apical positions [3, 11].

### Lead-related problems

In the study by Forleo et al. [5], the frequency of LV lead malfunction, defined as the need for re-programming or surgical revision, was significantly higher in the group of patients with bipolar leads. In our series, the same tendency was clearly observed, but the difference was not statistically significant. This difference could be partially explained by the longer follow-up period used in our study, in which phrenic stimulation events were observed in 2 additional patients from Group Q during the 9-month follow-up, while the frequency of this event at 3 months was the same as that reported in the previous study [5].

The use of a single lead to achieve the predetermined implantation goals was associated with a lower frequency of problems related to the LV lead



during follow-up. In the study by Forleo et al. [5] a single lead was also used in all of the patients from the quadripolar lead group, but more than 1 lead was used in 3 patients from the bipolar group. The use of more than 1 lead to some extent indicated a suboptimal result in many patients or greater difficulties in achieving the implantation goals, which manifested in a higher incidence of problems during follow-up. In addition, using a single lead to obtain an adequate result presents obvious financial advantages.

### Limitations of the study

This study presents certain limitations that must be considered to adequately analyze the presented results. While the study is not randomized, the choice of lead was not influenced by the patients' characteristics. The study includes a relatively low number of patients, which may explain the lack of statistical significance when comparing relevant variables that exhibited clear group-dependent trends, such as the "LV lead problems" variable. In this study, the radioscopy time and radiation dose data refer to the entire procedure, not only to the LV lead implant. However, it is acceptable to believe that the data are homogenous because in normal practice, the great majority of the radioscopy time in most cases of these procedures is related to the lead implantation. The patient follow-up was short, and no data were collected regarding the incidence of LV lead problems beyond the analyzed period or about the occurrence of other lead performance problems, especially regarding the quadripolar leads, about which we have limited information. However, to the best of our knowledge, this study has the longest follow-up time reported in the literature.

### Conclusions

The Quartet 1458Q quadripolar leads for LV pacing are associated with an excellent implantation success rate and mid-term performance. The

multi-programmability features of this quadripolar lead model and its associated generator facilitate implantation and help to minimize follow-up problems related to LV pacing.

**Conflict of interest:** none declared

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