Optimisation of Cardiac Resynchronisation Therapy with MultiPoint™ Pacing

Proceedings of a satellite symposium held at the EHRA Cardiostim Conference in Milan, Italy on 23 June 2015, funded by St Jude Medical

Reviewers: Antonio Curnis, David O’Donnell, Axel Kloppe and Žarko Čalović
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Optimisation of Cardiac Resynchronisation Therapy with MultiPoint™ Pacing

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Abstract
Cardiac resynchronisation therapy (CRT) using biventricular pacing is an established therapy for impairment of left ventricular (LV) systolic function in patients with heart failure (HF). Although technological advances have improved outcomes in patients undergoing biventricular pacing, the optimal placement of pacing leads remains challenging, and approximately one third of patients have no response to CRT. This may be due to patient selection and lead placement. Electrical mapping can greatly improve outcomes in CRT and increase the number of patients who derive benefit from the procedure. MultiPoint™ pacing (St Jude Medical, St Paul, MN, US) using a quadripolar lead increases the possibility of finding the best pacing site. In clinical studies, use of MultiPoint pacing in HF patients undergoing CRT has been associated with haemodynamic and clinical benefits compared with conventional biventricular pacing, and these benefits have been sustained at 12 months. This article describes the proceedings of a satellite symposium held at the European Heart Rhythm Association (EHRA) Europace conference held in Milan, Italy, in June 2015.

Keywords
Heart failure, cardiac resynchronisation, MultiPoint pacing

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Cardiac resynchronisation therapy (CRT) with biventricular pacing is an effective therapy in patients with advanced heart failure (HF) symptoms (New York Heart Association [NYHA] Class III or IV), an ejection fraction (EF) of 35 % or less and an intraventricular conduction delay (IVCD) of 120 ms or more.1,3 CRT has also been shown to be effective in the prevention of HF in relatively asymptomatic patients with wide QRS.3 However, CRT is underutilised among eligible patients.1 Approximately one-third of patients do not respond to CRT due to various factors, including anatomic difficulties and suboptimal lead placement. To increase the effectiveness of CRT, several experts have hypothesised that pacing at multiple left ventricular (LV) sites may provide more effective resynchronisation. A new approach involving MultiPoint™ pacing with the use of a single quadripolar lead (Quartet™ lead; St Jude Medical, St Paul, MN, US) has recently been proposed. This lead integrates four pacing electrodes, increasing the options in device programming. In order to present an overview of research to date on this technology, a satellite symposium, supported by St Jude Medical and chaired by Dr Antonio Curnis (Brescia, Italy), was held at the European Heart Rhythm Association (EHRA) Europace conference held in Milan, Italy, in June 2015.

Electrical Mapping to Optimise Heart Failure Outcomes Following Cardiac Resynchronisation Therapy

David O’Donnell, Austin Hospital, Melbourne, Australia

Dr O’Donnell began by stating that the response to CRT is suboptimal and a significant proportion of the poor response to CRT is due to poor positioning of the LV leads. In a typical left bundle branch block (LBBB), the response to routine CRT is 60 to 70 %, with an 8 % improvement in EF. Most physicians consider this a good response rate. However, if CRT is electrically mapped, outcomes can be further improved to yield an 80 % response rate and 12 % improvement in EF.

In order to improve CRT outcomes, we need to consider the factors that influence the response. These include patient selection: an increasingly smaller group are becoming eligible for CRT, meaning that a significant number of patients with HF are missing out on a treatment that may benefit them. Prior to electrical mapping, patients with atypical LBBB had a poor chance of responding to CRT. Randomised studies show response rates of around 40 % and EF improvements of 3%. Electrically mapped CRT nearly doubles the response in these patients (response rate 75 % and an 11 % improvement in EF).4 Patients with other conduction abnormalities, including a narrow QRS, right bundle branch block (RBBB) and non-specific IVCDs (NIVCD) have
Correct lead placement is also essential to optimise responses to CRT. Dr O'Donnell explained the challenges of optimising myocardial cell-to-cell transmission in CRT using the analogy of transmitting a message to a group of soldiers in such a way that each soldier receives the message as quickly as possible. However, CRT presents unique challenges such as scar (some soldiers do not pass on the message); conduction block (some soldiers only pass the message in one direction); functional block (some soldiers pass the message slowly or incompletely); and intrinsic conduction (some soldiers utilise intrinsic communication systems).

In other words, we need to focus on where to put the leads, the electrical conduction and the electrical map. In the same way that golf clubs and tennis racquets have a ‘sweet spot’ for an optimal shot, Dr O’Donnell suggested that there is a sweet spot in CRT. However, at present, we do not know where or how big it is. The remarkable improvement experienced by some patients with anterior leads suggests that in some people, the sweet spot is clearly bigger than others and in a broad left bundle with notching, it may be 2 to 3 cm, and the lead positioning is less crucial; whereas in cases of narrow QRS, it may be as small as 2 mm. This raises the questions: how close do we have to place the leads to achieve 90 % of the effect? If we do not find the right spot, are we making these patients worse? Large studies suggest that 10 to 15 % of patients deteriorate following CRT. However, this study found the right spot and the right patient with the lead in the wrong spot.

Dr O’Donnell presented his ideas as a series of concepts. Concept 1 is that there are better and there are worse places to pace in the heart. Others argue that this is incorrect and support their arguments with data that show the LV lead location does not impact on mortality or measures of response to CRT. Interpretations of the Multicenter Automatic Defibrillator Implantation Trial with Cardiac Resynchronization Therapy (MADIT-CRT) data have also led to the conclusion that the lead position is unimportant. However, this study concluded that, anatomically, it is difficult to determine where to put the lead, but areas of scar or the apical region should be avoided. This leads to Concept 2: anatomical placement is ineffective for finding the sweet spot. Therefore, if the sweet spot exists, it must be electrical. The reasons that anatomical placement fails is evident if we look at the different forms of septal activation in LBBB – a slide was presented of 20 different anatomical specimens of LBBB in 20 different patients – so it is unreasonable to expect that placing the lead in the same position in everyone will be beneficial.

A study of electrical activation in LBBB shows that there are multiple types of activation, and most people consider the typical LB that travels down the septum in a U shape but this activation pattern occurs in less than 50 % of all LBBB. A recent study of patients with LBBB found that the type of bundle block significantly influences response to CRT; an absence of ECG markers of residual LB conduction was predictive of a greater improvement in LV function with CRT.

A study found that markers of electrical dysynchrony, including the electrical delay at the LV pacing site (QLV) are predictive of response to CRT. Activation was measured as the time that the intrinsic electrical wave front detected in the RV lead takes to travel to the LV lead, a simple process that takes only seconds. If RV and LV electrograms are on time with each other, it is difficult to resynchronise the entire area effectively. Such patients are termed non-responders. In a typical non-responder, intrinsic RV–LV = 20 ms, QRSd = 145 ms, QLV = 15 %. In a typical responder intrinsic RV–LV = 120 ms, QRSd = 145 ms, QLV = 82 %, i.e., a large electrical delay. There was moderate correlation between intrinsic RV–LV electrical delay and delta LV versus absolute change in LVEF (p=0.03).

Many groups have validated this study. Electrical delay in the LV lead has been shown to be correlated with the haemodynamic response to CRT expressed as an intra-individual percentage change in the maximum rate of rise of LV pressure over baseline (dP/dt, derived from the mitral regurgitation Doppler profile). Later activated areas are associated with higher stroke volume and improved LV synchrony as determined by tissue Doppler imaging (TDI). The seminal electrical mapping study by Gold et al. found that a measured QLV interval is an electrical marker of delayed LV lead position and that long QLV is associated with better echocardiogram and clinical outcomes. The LV end-systolic volume and quality of life (QOL) response rates were statistically significant in the QLV quartiles used.

Another study examined the impact of electrical and anatomical location of the LV lead in relation to baseline QRS morphology on the CRT outcome. The best response was seen in a patient with an LB and an LV lead late in the QRS complex. Interestingly, patients with a non-left bundle and a narrow QRS had a similar benefit if the lead was placed in the correct spot. In other words, there is a statistical difference between having the wrong patient with the lead in the right spot and the right patient with the lead in the wrong spot. It can therefore be concluded that patient selection is important for successful outcomes in CRT, but it is only one component of a complex picture.

In the Targeted Left Ventricular Lead Placement to Guide Cardiac Resynchronization Therapy (TARGET) study, patients (n=220) underwent baseline echocardiographic speckle-tracking two-dimensional radial strain imaging and were then randomised 1:1 into two groups. In group 1 (TARGET), the LV lead was positioned at the latest site of peak contraction that was free from scar and non-apical. Group 2 (control) patients underwent standard unguided CRT. Patients were classified by the relationship of the LV lead to the optimal site as concordant (at optimal site), adjacent (within 1 segment), or remote (≥2 segments away). The primary endpoint was a 15 % reduction in LV end-systolic volume at 6 months. Secondary endpoints were clinical response (one improvement in NYHA functional class), all-cause mortality and combined all-cause mortality and HF-related hospitalisation. Response rates were higher in TARGET patients (83 % versus 65 %; p=0.003), and superior improvements in ESV and QOL were also reported. The major finding of this study was the importance of lead placement exactly at the latest zone, not merely adjacent to the latest zone (see Figure 1). These study data can be summarised in Concept 3: electrical mapping is effective and improves outcomes for patients undergoing CRT. Dr O’Donnell proceeded to describe how electrical mapping is used in his institution: following lead placement, activation is measured from proximal to distal, which shows an activation wave front. By using the electrical map to achieve a more distal lead placement, improvements can be gained. In the ongoing ‘moving the LV lead quad lead’ study,
in patients where the lead was moved, QLV at final position was 89 % whereas in patients where the lead was not moved, QLV in final position was 77 %, leading to Concept 3b; electrical mapping is effective and improves outcomes for patients undergoing CRT. However, electrical mapping requires moving the lead if it is not in the late zone.

There is a reluctance among cardiologists to move leads and, in these situations, a quadripolar lead is useful. A recent multicentre study of consecutive implants and a quadripolar lead has shown that the mean difference in intrinsic electrical activation of the usable electrodes was 30 ms (3 to 55 ms). Quadripolar leads reduce phrenic nerve stimulation, reduce high thresholds and are user friendly; however, the most compelling argument for their use is the fact that resynchronisation parameters can be improved by 20 ms by picking the best versus worst electrode.

The optimal pacing site appears to be determined by the fastest pathway of activation from the LV and RV electrodes. If it takes longer to move from one side of the heart than from another, the answer is to move the leads. The greater the difference in timings left–right versus right–left, the worse the outcomes, i.e., delta LV. In a recent study, the RV-paced delay (RVp-LV) and LV-paced delay (Lvp-RV) were measured during RV-only pacing and LV-only pacing, respectively. The timing difference between the LVP-RV and RVp-LV was termed the delta LV. Results showed that significant intrinsic electrical delay and shorter delta-LV both predicted response, even when LV leads were implanted in the targeted mechanically delayed segment. Such assessments of electrical dyssynchrony may be used to determine optimal lead positions and response to CRT.

In conclusion, electrical mapping is very effective but is not yet easy. Anatomical LV lead placement does not enable optimal patient outcomes but electrical mapping can guide LV placement and improve outcomes for patients undergoing CRT. Increased experience will improve our expertise at mapping CRT. However, by using the lead with the most poles and the device with the most programming options, we can future proof our patients.

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### Clinical Evidence Demonstrating the Benefit of MultiPoint Pacing

**Cardiac Resynchronisation Therapy**

Axel Kloppe, Bergmannsheil Bochum, Germany

Dr Kloppe began his presentation by discussing a 2008 multicentre single-blind crossover study that randomised patients with congestive HF (n=40) either to triventricular (one RV and two LV leads) or biventricular (one RV and one LV lead) stimulation. The primary endpoint was quality of ventricular resynchronisation (Z ratio). The study did not find a significant change in Z ratio but concluded that CRT with triple-site ventricular stimulation was safe and resulted in a significantly higher LVEF and smaller LV end-systolic volume and diameter.

Since this study, quadripolar leads have been developed. A 2013 study (n=21) compared biventricular and multisite pacing with a quadripolar LV lead. Using an acute pacing protocol, four configurations of multisite and simultaneous RV pacing were tested. In the majority (84 %) of patients, MultiPoint pacing improved LV dp/dtmax compared with biventricular pacing. Only three patients with MultiPoint pacing (one who was a super-responder) experienced no significant additional effect from MultiPoint pacing.

In a prospective multicentre study (n=40), a CRT defibrillator incorporating a quadripolar lead was programmed to deliver MultiPoint pacing with eight different configurations of timing delays. The configuration that yielded the best echocardiographic measurement for each patient was defined as ‘optimal MultiPoint pacing’. The endpoint was analysis of contractility expressed as global radial strain of the opposing walls and stroke volume LV output tract velocity timed intervals (LVOT VTIs). Compared with conventional CRT, the mean peak radial strain was significantly higher for the optimal MultiPoint pacing configuration (18.3 ± 7.4 versus 9.3 ± 5.3 %; p<0.001). The median delay between LV1 and LV2 was 55 ms, and between LV2 and RV was 20 ms. In a subanalysis, no difference was seen between ischaemic and nonischaemic patients. The proportion of patients who exhibited improvements in LVOT VTI with at least one MultiPoint pacing intervention over conventional CRT is shown in Figure 2, and suggests that low and non-responders might derive more benefit from MultiPoint pacing.

Most recently, a study by Pappone et al. investigated MultiPoint pacing in 44 consecutive patients in an acute setting. Following CRT implantation, consecutive patients (n=44) were randomised to receive biventricular pacing with either conventional LV pacing (CONV) or MultiPoint pacing (see Figure 3). In each case, an optimal pacing configuration was determined based on intra-operative pressure-volume (PV) loop measurements. The primary endpoint was reduction in LV end-systolic volume (LVESV) of ≥15 %. The delay between LV1 and LV2 was 26 ± 15 ms and between LV2 and RV was 10 ± 9 ms. After 3 months, 50 % of CONV patients and 76 % of MultiPoint pacing patients were classified as responders. ESV reduction, EF increase and NYHA class reduction relative to baseline were significantly greater in the MultiPoint pacing group than in the CONV group. In terms of aetiology, non-ischaemic patients had a significant reduction in LVESV compared with ischaemic patients, but no differences were seen in other parameters. A significant increase in MultiPoint pacing group in contractility, stroke volume and EF was seen with MultiPoint pacing. In addition, the best MultiPoint pacing improved acute diastolic function, i.e., change from baseline.

In 2015, Pappone published 12-month
Another recent study compared biventricular pacing and MultiPoint pacing in a group of 29 patients with a high QRS. The effect of MultiPoint pacing, by means of simultaneous pacing from distal and proximal dipoles, was investigated at any available site, an average of 3.2 pacing sites per patient, and a total of 92 measurements. An increase in LV electrical delay (Q-LV) at any site was seen even with MultiPoint pacing relative to biventricular pacing when taking the best and worst sites. Q-LV was measured at each location, along with the increase in LVEDP/dtmax (maximum rate of rise of LV pressure) obtained by biventricular pacing and MultiPoint pacing. The effect of MultiPoint pacing, by means of simultaneous pacing from distal and proximal dipoles, was investigated at all available sites. Compared with biventricular pacing at any LV site, MultiPoint pacing yielded a small but consistent increase in haemodynamic response. A correlation between the increase in haemodynamics and Q-LV on MultiPoint pacing was observed for all measurements, including those taken at the best and worst sites. The MultiPoint pacing-induced improvement in contractility was associated with significantly greater narrowing of the QRS complex than conventional biventricular pacing. A good correlation was observed between electrical delay and haemodynamic improvement. A good correlation was observed between electrical delay and haemodynamic improvement.

In conclusion, a growing body of clinical data have demonstrated that CRT with MultiPoint pacing can significantly improve acute cardiac contractility and haemodynamic parameters compared with conventional pacing. MultiPoint pacing can further augment the well-described systolic benefits of CRT, likely by better synchronising LV contraction and/or recruiting additional LV myocardial tissue. The MultiPoint pacing-induced improvement in contractility was associated with significantly greater narrowing of the QRS complex than conventional biventricular pacing. However, much remains poorly understood, including the optimal timing of LV1 to LV2 to RV.20

Strategies for dealing with non-responders include electrogram-based delay optimisation, which is fast, simple and non-invasive, but has not been associated with any benefit in the FREEDOM or SMART-AV trials.25,26 Echo-based delay optimisation is time-consuming, measurements may be inconsistent and its clinical benefit is questionable. Targeting the LV lead to the latest activation has been shown to be effective but coronary sinus anatomy may prevent access to the ideal location. The limitations of these strategies have led to the development of MultiPoint pacing LV pacing.

A 2000 study of HF patients with LBBB showed that dual-site pacing gave a greater improvement in systolic function compared with single-site pacing.24 Subsequent studies investigated triple-site pacing25 and concluded that multiple LV pacing sites capture a larger area and reduce dyssynchrony, but involve increased procedure times and increased contrast exposure, as well as lower implant success and the requirement for a Y adaptor or second LV lead connected to the atrial port of the device.

**Management of Non-responders to Cardiac Resynchronisation Therapy with MultiPoint Pacing**

Žarko Čalović, IRCCS Policlinico San Donato, San Donato Milanese, Italy

Dr Čalović started by examining the percentage of non-responders to CRT. A 2010 evaluation of different studies concluded that agreement is poor among different studies, since different response criteria are used, and concluded that 30 to 50 % of patients do not respond to CRT.21

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The use of MultiPoint pacing involves a lead with four poles with an ability to pace from three ventricular sites with programmable delays. In a scarred heart, we often see dispersal of the wave fronts of the electrical current. Pacing at two points simultaneously overcomes these obstacles. As previously discussed, numerous studies have demonstrated the acute and mid-term benefits of MultiPoint pacing in improving electrical propagation, acute haemodynamics and dyssynchrony.\textsuperscript{25–28,35–37} Remaining unanswered questions include: what are the long-term benefits of MultiPoint pacing? Can MultiPoint pacing help patients already receiving CRT?

Determining the optimal pacing vector and inter-ventricular delay can be challenging in conventional CRT. With MultiPoint pacing, the addition of a second LV pulse with another programmable delay gives even more programming options. The MultiPoint pacing loop study evaluated two methods of MultiPoint pacing vector combination selection and multiple delay combinations. In this patient cohort, an empirical method of selecting MultiPoint pacing pacing vectors based on maximising anatomical spacing between LV1 and LV2 cathodes resulted in the best dP/dt response more often than an electrical delay-based selection method. Moreover, pacing with 5 ms LV1–LV2 delay produced the best dP/dt response more often than pacing with 40 ms LV1–LV2.\textsuperscript{27}

Recently, Pappone published 12-month follow-up data from this study.\textsuperscript{28,38} The trend observed at 3 months was sustained; LVESV and EF were significantly improved in the MultiPoint pacing group relative to the CONV group. A clinical benefit was also seen: improvement of more than two NYHA classes was seen in a much higher proportion of MultiPoint pacing patients compared with conventional pacing. According to the definition of response (ESV reduction of ≥15 % and alive status at 12 months), 67 % of the overall patient population were responders, with a 76 % responder rate in the MultiPoint pacing group compared with 57 % in the CONV group. This was further subdivided into super-responders (ESV reduction ≥30 %), responders (ESV reduction ≥15 and <30 %), non-responders (ESV reduction ≥0 and <15 %) and negative responders (ESV increase). The MultiPoint pacing group showed a lower rate of negative responders (10 versus 25 %) and a higher rate of super responders (33 versus 14 %) compared with the CONV group (see Figure 4).\textsuperscript{28} An example of acute haemodynamic measurements and echo measurements were given in a super responder: these included a decrease in EDV from 310 ml at baseline to 235 ml at 3 months and 211 ml at 12 months. The decrease in EF was 35 % at baseline and 41 % at both 3 and 12 months.\textsuperscript{28}

Dr Calovic next posed the question: can MultiPoint pacing improve the response in patients receiving conventional CRT? At CRT implant programmed with simultaneous biventricular pacing, patients were assessed by an echo exam (LVEF, LVEDV, LVEF) as well as undergoing NYHA class assessment. At 12 months, patients underwent follow-up assessments and CRT programming was switched to MultiPoint pacing. Further follow-up assessments were performed at 16 months. Following the switch, the two non-responders to conventional CRT both became responders with MultiPoint pacing while experiencing an additional reduction in ESV of -33 % and -20 % and an improvement in EF of +15 % and +4 % at 16 months relative to the 12-month exam. Five of the six responders to conventional CRT remained responders with MultiPoint pacing, with four patients experiencing additional ESV change of at least -10 %. In terms of NYHA class changes, all patients were Class II pre-implant, all improved to Class II at 12 months and after 4 months of MultiPoint pacing, four patients improved to Class I while the remaining five patients remained in Class II.\textsuperscript{28}

In conclusion, MultiPoint LV pacing in a single coronary sinus branch results in significant improvements in acute haemodynamic function and long-term CRT response relative to conventional biventricular pacing. Non-responders to conventional CRT may benefit from activating MultiPoint pacing and may be converted to responders. In addition, CRT responders may experience additional LV remodeling and/or increased LV function beyond that received from the conventional therapy.

**Summary and Concluding Remarks**

Although technological advances have improved outcomes in patients undergoing biventricular pacing, the optimal placement of pacing leads remains challenging and there is a need to improve response rates to CRT and optimise patient selection. MultiPoint pacing using a quadripolar lead increases the possibility of finding the best pacing site. In clinical studies, use of MultiPoint pacing in HF patients undergoing CRT has been associated with increased haemodynamic and clinical benefits compared with conventional pacing, particularly in patients with the least improvement from biventricular pacing. Use of MultiPoint pacing results in a smaller number of non-responders and further improvements in those that do respond. While data have shown that benefits are sustained at 12 months, there is a need for further long-term studies to investigate the performance and reliability of MultiPoint pacing.
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