

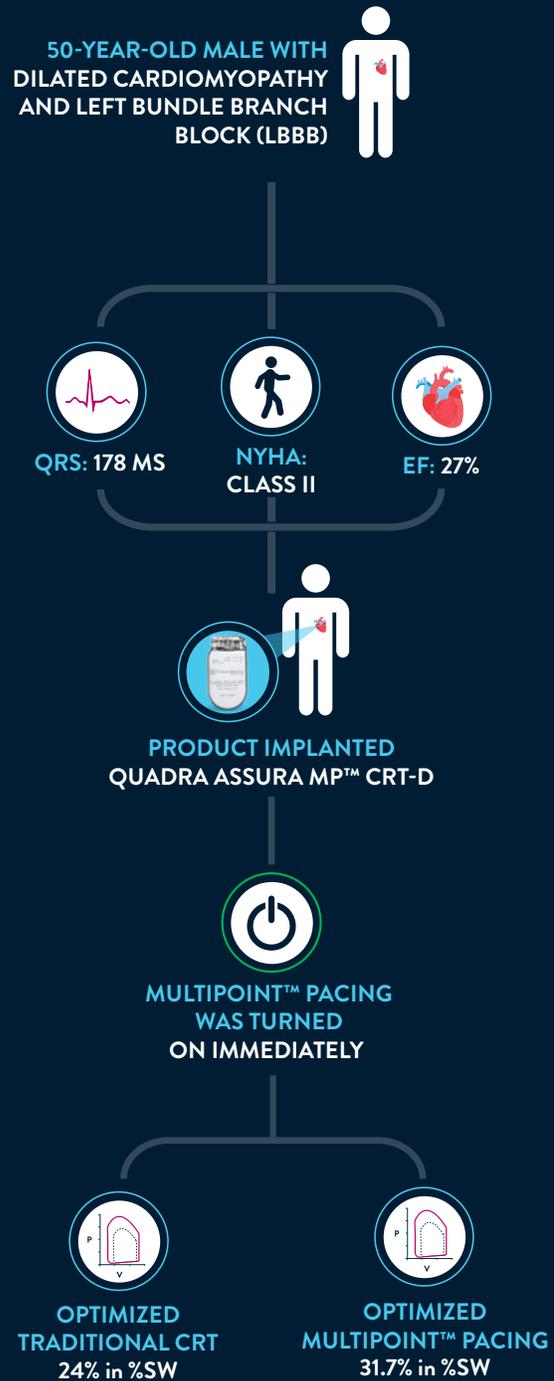


**AN OPTICARE-QLV
CASE STUDY:
PRESSURE-VOLUME
LOOPS TO OPTIMIZE CRT
WITH A QUADRIPOlar
(QUARTET LEAD) LEFT
VENTRICULAR LEAD**

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MULTIPOINT™ PACING CASE STUDY

**HEMODYNAMIC CHANGES IN A
PATIENT UNDERGOING CARDIAC
RESYNCHRONIZATION THERAPY**



INTRODUCTION

This is a case report of a 50-year-old male with dilated cardiomyopathy and left bundle branch block (LBBB) who underwent cardiac resynchronization therapy (CRT) implantation. The patient participated in a study conducted in the UMC Utrecht (the Netherlands) optimizing CRT settings with pressure-volume loop measurements; the OPTICARE-QLV study.

This patient suffers from heart failure, NYHA functional Class II with a LV ejection fraction of 27% on MRI. A dilated cardiomyopathy was diagnosed, as MRI showed no signs of delayed enhancement. Comorbidity was paroxysmal atrial fibrillation. ECG: QRS-width of 178 ms with a LBBB according to Strauss criteria (Figure 1).

Figure 1. Baseline ECG recording, showing an LBBB.

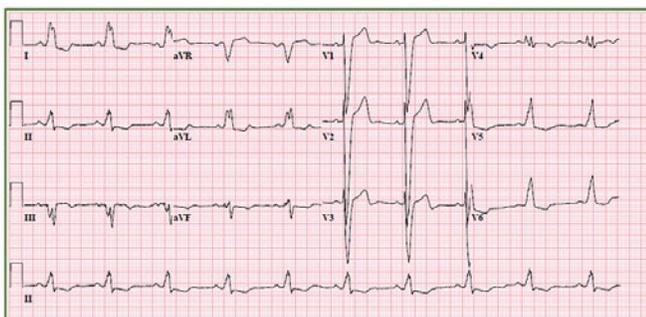


Figure 2A. An RAO 0 recording during CRT implantation. The abbreviations (D1, M2, M3 and P4) represent the four quadripolar electrodes of the Quartet™ lead.

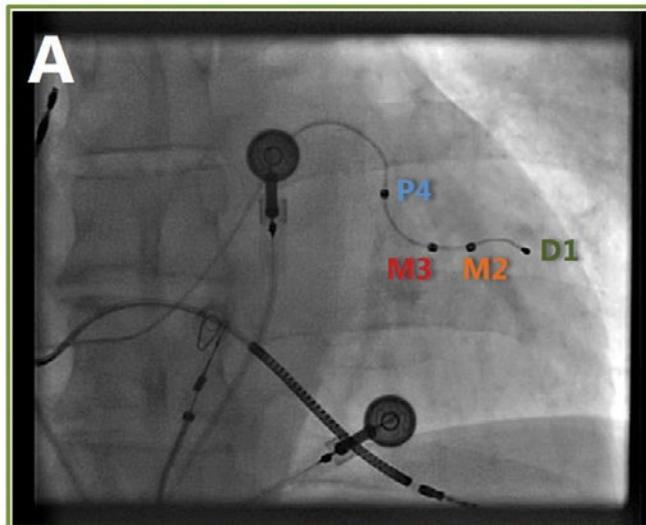
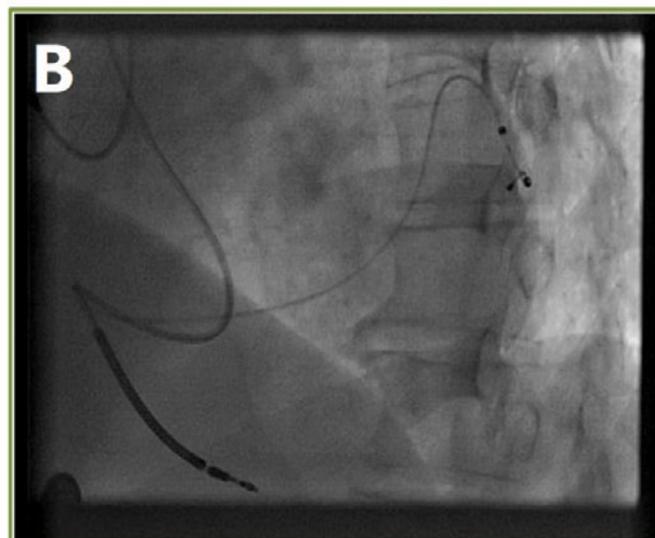


Figure 2B. Represents the LAO 40° recording.



METHODS

A CRT-D device (Quadra Assura MP™, Abbott) was successfully implanted with a Quartet™ quadripolar LV lead. First, the electrical delays between onset of QRS-complex and local LV-depolarization were measured (QLV) of each quadripolar electrode. Next, a pressure volume loop catheter (CD Leycom™, Zoetermeer, the Netherlands) was inserted via the femoral artery and placed in the LV cavity.

Pacing settings were optimized for all four quadripolar electrodes, using the RV-coil as anode. Four atrioventricular delays (AVD) were implemented, using 80, 60, 40 and 20% of the intrinsic atrial paced to RV-sensed delay. All settings were programmed using an interventricular delay (VVD) of -40 ms (LV first). DDD pacing was performed 5 to 10 beats above intrinsic rhythm. PV-loops (Figure 3) were recorded for 60 beats for each pacing setting and compared to preceding and subsequent baseline recording of 30 beats each (AAI pacing). The resulting parameter, increase in stroke work compared to baseline (%SW) was recorded and calculated by offline analysis for each setting and electrode.

The results of %SW were plotted against the used AV-delay, and a second order polynomial curve was fitted to the data. The maximal increase of the fitted line was used as the theoretical maximal benefit of the quadripolar configuration.

Finally MultiPoint™ Pacing was implemented, using the electrodes D1 and P4 of the quadripolar lead. Three settings were compared: simultaneous MultiPoint™ Pacing with D1 and P4 (D1-RVcoil and P4-RVcoil with a minimal inter left ventricular delay (ILVD) of 5 ms and a VVD of -35 ms), D1 and P4 with an ILVD of 35 ms and VVD of -5 ms, and finally the electrode sequence was switched, pacing P4 first and D1 second with the same delays. All configurations were tested with the four previous mentioned AVD's.

Figure 3A. PV-loops of optimal biventricular pacing with D1-RVcoil with a AVD of 110 ms and VVD of -40 ms (green loop).

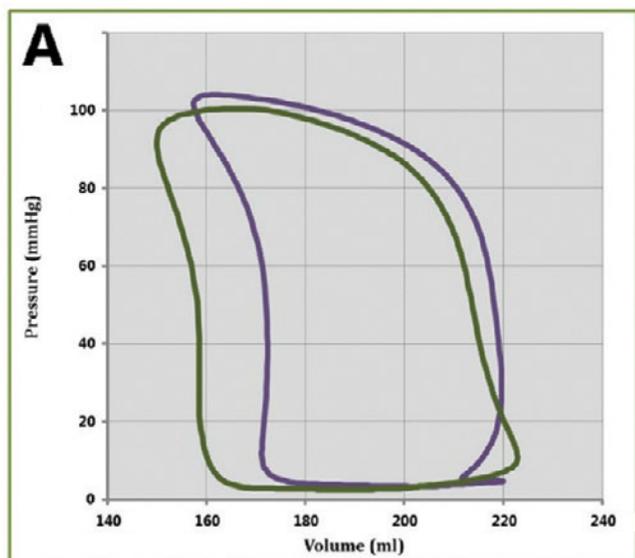


Figure 4A. Displays results of D1 (green), M2 (orange), M3 (red) and P4 (blue) using RV-coil as anode. D1-RVcoil has the maximal increase in %SW (24.0%).

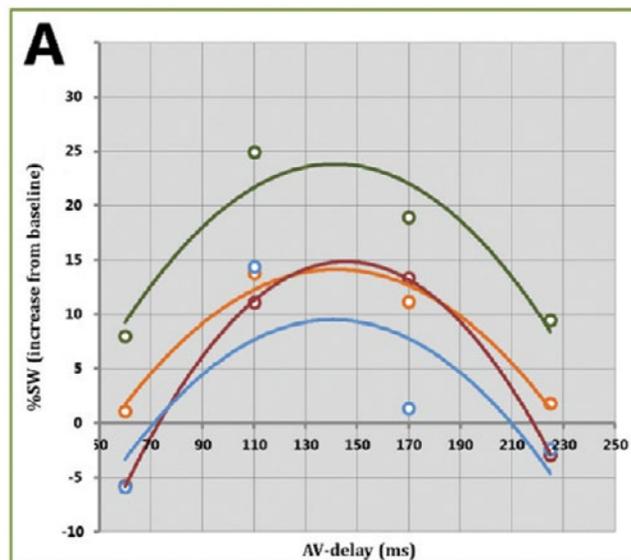


Figure 3B. Displays the PV-loop of the optimal MultiPoint™ Pacing setting in orange (P4D1, AVD 170 ms, VVD -5 ms and ILVD 35 ms.) The purple loops are the average of two neighboring baseline recordings.

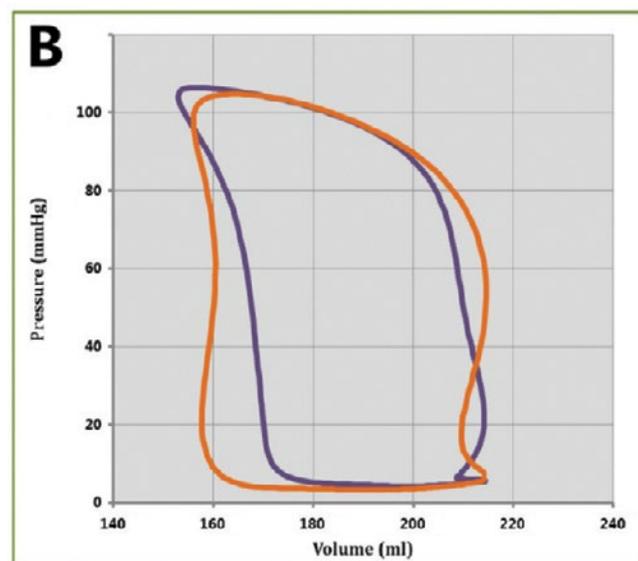


Figure 4B. Displays MultiPoint™ Pacing, with D1 and P4 simultaneous (green), D1 and P4 with an ILVD of 35 ms (orange) and P4 and D1 with an ILVD of 35 ms (red). P4D1, ILVD 35 ms gave the maximal increase of %SW (31.6%). Dots represent measured %SW per electrode and AV-delay, the colored lines represent the fitted curves.



RESULTS

The optimal pacing configuration using a quadripolar lead (D1-RVcoil, AVD 140 ms and VVD -40 ms) gave an acute increase of 24.0% in %SW (Figure 4A) compared to baseline. The electrode configuration with the least optimal response was P4-RVcoil, with an increase of 9.0%. MultiPoint™ Pacing gave a maximal benefit in %SW of 31.7% on D1 and P4 with an inter left ventricular delay of 35 ms (AVD 145 ms, VVD -5 ms, ILVD 35 ms (Figure 4B). There was no correlation between %SW and QLV (QLV results, D1: 153 ms, M2: 164 ms, M3: 162 ms, P4: 153 ms).

CONCLUSION

This case report shows the acute hemodynamic benefit of optimizing CRT with a quadripolar LV lead, using multiple AV-delays and pressure-volume loops. It further advocates the potential benefit of MultiPoint™ Pacing. More cases are needed to confirm these results, and will follow in the OPTICARE-QLV study.

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Brief Summary: Please review the Instructions for Use prior to using these devices for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

Quartet™ LV lead

Indications and Usage: The Quartet lead has application as part of an Abbott Biventricular system.

Contraindications: The use of the Quartet lead is contraindicated in patients who:

- Are expected to be hypersensitive to a single dose of 1.0 mg of dexamethasone sodium phosphate.
- Are unable to undergo an emergency thoracotomy procedure.
- Have coronary venous vasculature that is inadequate for lead placement, as indicated by venogram.

MultiPoint™ Pacing and SyncAV™ CRT Technology

Indications: Abbott ICDs and CRT-Ds are intended to provide ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life-threatening ventricular arrhythmias. AF Suppression™ pacing is indicated for suppression of paroxysmal or persistent atrial fibrillation in patients with the above ICD indication and sinus node dysfunction. In patients indicated for an ICD, CRT-Ds are also intended to provide a reduction of the symptoms of moderate to severe heart failure (NYHA Functional Class III or IV) in those patients who remain symptomatic despite stable, optimal medical therapy (as defined in the clinical trials section included in the Merlin™ PCS on-screen help) and have a left ventricular ejection fraction less than or equal to 35% and a prolonged QRS duration to maintain synchrony of the left and right ventricles in patients who have undergone an AV nodal ablation for chronic (permanent) atrial fibrillation and have NYHA Class II or III heart failure.

Contraindications: Contraindications for use of the pulse generator system include ventricular tachyarrhythmias resulting from transient or correctable factors such as drug toxicity, electrolyte imbalance, or acute myocardial infarction.

Adverse Events: Implantation of the pulse generator system, like that of any other device, involves risks, some possibly life-threatening. These include but are not limited to the following: acute hemorrhage/bleeding, air emboli, arrhythmia acceleration, cardiac or venous perforation, cardiogenic shock, cyst formation, erosion, exacerbation of heart failure, extrusion, fibrotic tissue growth, fluid accumulation, hematoma formation, histotoxic reactions, infection, keloid formation, myocardial irritability, nerve damage, pneumothorax, thromboemboli, venous occlusion. Other possible adverse effects include mortality due to: component failure, device programmer communication failure, lead abrasion, lead dislodgment or poor lead placement, lead fracture, inability to defibrillate, inhibited therapy for a ventricular tachycardia, interruption of function due to electrical or magnetic interference, shunting of energy from defibrillation paddles, system failure due to ionising radiation. Other possible adverse effects include mortality due to inappropriate delivery of therapy caused by: multiple counting of cardiac events including T waves, P waves, or supplemental pacemaker stimuli. Among the psychological effects of device implantation are imagined pulsing, dependency, fear of inappropriate pulsing, and fear of losing pulse capability.

Refer to the User's Manual for detailed indications, contraindications, warnings, precautions and potential adverse events.

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