Challenges and Solutions for Difficult Implantations of CRT Devices: The Role of New Technology and Techniques

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Difficult CRT Device Implantation Procedures. Introduction: Cardiac resynchronization therapy (CRT) can markedly improve heart failure treatment in selected patients, but left ventricular (LV) lead implantation can be difficult or optimal lead position not obtainable.

Methods: This review examines newer techniques and technologies to optimize implant success. Goals of implant include placement of the LV lead in a coronary vein near the midlateral left ventricle with good lead stability, adequate thresholds, and no phrenic nerve stimulation. We will examine methods to access difficult and tortuous veins, test multiple veins for the best pacing site, and avoid complications. Newer technologies that will be discussed include magnetic wire navigation using Stereotaxis™, endoscopic, and CT-guided approaches, and nontraditional methods such as pericardial puncture for epicardial LV lead placement.

Conclusion: The methods discussed here may help to make CRT implant safer, faster, and more successful.


biventricular pacing, cardiac resynchronization therapy, congestive heart failure

Introduction

Cardiac resynchronization therapy (CRT) improves quality of life and prolongs survival in appropriate patients with QRS prolongation or left ventricular (LV) dysynchrony. With newer lead and lead delivery systems, 85–95% of patients have a lead implanted in the coronary veins. Nevertheless, many clinical studies have shown a sizeable percentage of patients—up to 30% (range: 15–40%)—fail to respond to CRT therapy. There are many reasons for an inadequate response to CRT therapy, but there is no chance of a response without a successful LV lead in an appropriate branch vessel (Table 1). A successful implant typically involves placing a lead in a midlateral, posterolateral, or anterolateral LV vein, but not in an anterior vein. However, many LV lead implants remain difficult and technically challenging. About 10% of attempts to place LV leads are ultimately unsuccessful. Newer technologies, better tools, and improved techniques should result in improved success rates, decreased procedure time, and decreased fluoroscopic exposure for the implanting physician.

Even with multiple new tools including a variety of guide catheters now available, telescoping inner sheaths, and better leads, many implants remain challenging. We will address additional new technical tricks and future directions including magnetically driven wires and leads, endoscopically visualizing veins, CT- or MRI-guided access, epicardial access, and an epicardial approach from the endocardium (Table 2). These new technologies, better tools, and improved techniques should result in improved success rates, decreased procedure time, and decreased fluoroscopic exposure for the implanting physician.

Reasons for Difficult Implants

There are multiple reasons for difficult LV lead implants. A recent clinical trial of a new LV lead catalogs the problems related to LV lead implantation (Table 3). These include inability to cannulate the coronary sinus (CS), inability to cannulate or find an adequate-sized LV vein overlying the lateral wall, and inability to find a position in a lateral vein that does not result in phrenic nerve stimulation. LV vein problems include an absence of adequate veins, difficult vein takeoffs, tortuous branch veins, early takeoff of LV lead branches, too large or too small veins, and inability to find a site in a branch vein where the phrenic nerve is not stimulated.

Solutions

CS Access Solutions

Endocardial visualization catheter

Inability to obtain CS access is one of the most common causes of implant failure. Infrared fiberoptic endoscopy has been used to directly visualize and cannulate the CS os in dogs by Nazarian et al. They were also able to visualize and subselect coronary veins. In 10 healthy dogs, a steerable infrared fiberoptic endoscope (FIRE™, 7 Fr, Cardio-Optics, Inc., Boulder, CO, USA) was inserted into the right atrium via the right internal jugular vein. The inferior vena cava ostium, tricuspid valve, and eustachian ridge were readily visualized. These landmarks were used to guide CS identification. After visualizing the CS os, the endoscope was advanced into the CS lumen and LV venous branches were visualized. A guide sheath was then advanced over the endoscope for CS access. This was done with minimal fluoroscopy and no contrast.

The first human experience with this device was recently reported by Anh et al. Fifty-eight patients had CRT implants using a steerable fiberoptic EVC (endocardial visualization catheter). This catheter is an 8-Fr deflectable fiberoptic...
TABLE 1
Reasons for CRT Therapy Failure

| Technical failure of procedure: Vessel |
| Distribution/Size/Navigation/Failure of CS cannulation |
| Failure to access CS |
| Inability to deliver LV lead to CS branch vessel due to small size, tortuosity, or other anatomic problem |
| Lack of adequate capture threshold |
| Diaphragmatic (phrenic nerve) stimulation |
| LV lead instability |
| Resynchronization response is absent |
| LA-LV timing |
| LV-RV timing |
| Akinesis of lateral LV wall |
| Lack of preimplant dyssynchrony |

endoscopy with a compliant distal balloon. There is a lumen for contrast injection or a guide wire. The EVC was able to visualize the CS in all 58 cases with a mean time from insertion to visualization of 6 ± 5 minutes. In 54/58 patients, the CS was successfully cannulated with the EVC. In a patient with unsuccessful cannulation, a valve that prevented access could be seen with the EVC. The limitations of this technique are that no studies have compared this to the standard methodology for cannulating the CS, and the ability to visualize the CS may not make it easier to place the lead in a branch vein. The cost of this additional equipment must be considered. Finally, only rarely can the CS not be cannulated with newer sheaths that are now available.

Intracardiac echocardiography (ICE)

ICE has also been used to visualize the CS for LV lead placement in difficult cases. Shalaby used an ICE catheter (Ultra ICE® 9F/9 MHz, Boston Scientific, Boston, MA, USA) in 10 consecutive patients for CS access. All attempts were successful. He placed the ICE catheter through a sheath into the right ventricle. Pulling the sheath and ICE catheter back together as a unit, he visualized the tricuspid valve, and then with counter clockwise torque, the system was further withdrawn to the cavotricuspid isthmus. The CS was then identified, and the system advanced into the CS. With further advancement, LV venous branches could be seen coming off the CS. In 7 of 10 patients, no fluoroscopy was used during access. In 3 patients, fluoroscopy was required after the catheter became lodged in small posterolateral branches. No complications occurred. An additional benefit was the ability to see the branch LV veins, and thereby avoid the need for contrast venography. The limitations of this technique are the additional cost, the infrequent occurrence of failure to cannulate the CS, and the lack of randomized trials comparing this technique to standard techniques.

Access to Difficult Anatomy

Coronary Vein Solutions

In many patients, the desired vein has an acute angle of takeoff, which makes it difficult to access. Even when the vein can be subselected with a guide wire, there may be inadequate support to track the lead over the wire without prolapse of the guide wire back into the CS.

The traditional method for gaining access to an acute takeoff is with a preformed sheath such as a LIMA catheter loaded over a wire. This, however, risks dissecting the LV vein. Care must also be taken to choose the correct angled guide. A curve that is too big is difficult to turn; one that is too small will not reach into a sharply angled vein.

Another approach is to use a lead with a preformed curve (e.g., Attain™, Medtronic, Minneapolis, MN, USA) to angle into the vein and advance the guide wire forward from the lead tip. However, wires are not as torqueable when in a lead with a curved tip, so navigating the wire distally may be difficult.

Mead et al. described a technique of inflating a pulmonary artery catheter balloon in the CS just distal to a difficult takeoff vein. This provided support to advance an angioplasty wire out of the angulated vein without the wire prolapsing back into the CS. After the wire is deployed, the balloon catheter is removed, and the lead placed over the wire.

Magnetic Navigation

A newer approach is to use a Niobe® magnetic navigation system (Stereotaxis, St. Louis, MO, USA). This system will
steer the wire tip as directed by a magnetic field. The system employs an arrangement of large natural magnets external to the body that swing into position on each side of the patient. A spherical magnetic field with a diameter about the size of a volleyball is positioned around the heart. The magnetic field direction is digitally controlled and directs the magnetic distal tip of the guidewire inside the heart using a 0.08–0.10 tesla field strength. The desired magnetic field vectors can be set by tracing target vessels on orthogonal fluoroscopic views of two coronary venograms (at least 40° of separation) on the computer workstation or a tableside touch screen to create a three-dimensional (3D) vessel roadmap (Fig. 1). A control computer then generates a composite magnetic field that interacts with the tiny magnet on the guidewire and deflects the wire to align parallel with the magnetic field.13 The wire can be directed at any angle and continuously turned for multiple sharp bends in the vein. The system will store previous venous approaches so multiple veins can be accessed and LV thresholds and phrenic nerve pacing can be assessed, and then facilitate the return to the best lead location. This allows the operator to move away from sites with marginal, but acceptable, thresholds or diaphragmatic stimulation without fear of not being able to return if that is later shown to be the best site. The system also enables directing the guidewire into branches off a main posterior or lateral vein. This will allow for better stability by placing the lead tip in a smaller branch. Better lead positions can be obtained since the lead can be placed in a midbasal position side branch rather than being advanced further toward the apex for a stable site. Tortuous branches can be entered steering the wire around twisting curves (Fig. 2).

The same technology has been used in conjunction with a magnetically enabled mapping catheter (Tangent® II, Stereotaxis) and software navigation presets, searching algorithms to facilitate cannulation of the CS in cases with difficult access. This technique is likely to be helpful in difficult cases and may significantly reduce radiation. However, there are no randomized clinical trials comparing this tool to standard guide catheters and inner sheaths. Additionally, the cost of this system is substantial. Optimal use of this technology requires a learning curve and enough usage to become familiar with the tools and techniques of venous navigation through remote wire movement. There are no comparative studies of this technology with standard techniques using newer conventional guide wires and guiding tools. Additionally, the Stereotaxis™ technology is constantly being improved with newer guide wires and development of guiding sheaths and other tools. This technology offers the possibility of being able to subselect small branches of the coronary venous system in areas with desirable physiology.

**Double Guidewire and Retained Guidewire**

A major difficulty in placing LV leads is getting the lead to follow a guidewire through an acute angle. The lead may simply prolapse the guidewire back out of the vein branch and into the CS. Common solutions to this problem are to advance the guidewire as far out the vein as possible, sometimes even coming back into the CS via anastamoses. This allows extra support when pushing the lead through the acute angle. One technique that gives even more support is to pull the guidewire back as you advance the lead. When inner catheters that can subselect an acute vein and allow direct insertion of an LV lead are developed, they can be used for support. This is not yet commercially available from any manufacturer.

Another way to approach this problem is to double-wire the acute takeoff vein. As described by Chierchia,14 two wires are placed in the sharply angulated vein that “opens the vein,” reducing tortuosity and providing much more support. The second “support” wire can be a stiffer, heavier wire, such as a 0.018 mm wire or larger. This allows tracking of the lead over the first wire.

Even after a difficult access, the best lead site can be unstable. The vein may be too large in diameter to anchor the lead, and then rapidly taper off so the lead cannot be advanced into a narrower, more distal site. Alternatively, the more stable
site may have phrenic nerve stimulation or be too distal for effective resynchronization. De Cock et al.\textsuperscript{15} described a retained guidewire technique to anchor leads after experiencing multiple dislodgements. With the lead in optimal position, a guidewire is advanced through the lead out into a distal branch. The wire is then coiled with clockwise rotations to anchor it. The proximal end of the wire is cut and left in the proximal lead. A wire with a polymer, rather than metallic, coating must be used to avoid electrical interference. The authors have had good success with this technique in a small number of patients. Kowalski used CS stents to anchor unstable LV leads. The stent is deployed within the CS in the space between the lead and the vein that pins the lead to the vein. In two patients with previously dislodged leads, the leads remained stable at three- and five-month follow-up.\textsuperscript{16} A major concern with these last two techniques is that the LV lead will not be accessible if lead extraction is necessary in the future.

Another technique that has been described for placement of LV leads when access is limited is coronary vein balloon angioplasty. In one report, Hansky et al.\textsuperscript{29} described performing venoplasty for LV lead placement in 5 of 218 patients or 2.29%.\textsuperscript{17} In this series, most patients had ischemic cardiomyopathy and two patients had prior coronary artery bypass surgery. In most cases, balloon angioplasty was performed because of target vein stenoses, but this procedure has been increasingly performed to create channels of sufficient caliber for lead placement. Importantly, the veins are relatively noncompliant and often require inflation to pressures up to 10 bar. This technique has been used extensively by several centers; however, the results of this technique in a large group of patients are unknown. Finally, there is a possibility that this technique could result in difficulty if future if lead extraction becomes necessary.

**Epicardial Lead Placement**

**New Techniques for Epicardial Lead Placement**

Sometimes the LV lead cannot be placed successfully in an LV vein, or there is diaphragmatic stimulation from most venous sites. In these instances, patients may go to surgery for epicardial lead placement. Future methods may include transvenous access to the pericardial space. Michelson et al.\textsuperscript{18} reported gaining access to the pericardial space in eight pigs with controlled punctures through the anterior superior vena cava or right atrial appendage using a Brockenbrough needle. He was able to place both active and passive fixation leads into the space and pace the left ventricle. Four pigs developed pericardial effusions after this procedure. In contrast, Shivkumar reported a case where transseptal puncture and LV endocardial lead placement was used to attain CRT therapy.\textsuperscript{19}

Another approach is to use CT guidance for percutaneous transthoracic placement of LV leads. Dickfeld et al.\textsuperscript{20} used real-time CT to find the safest pericardial approach in four pigs. A 17G needle was advanced from an anterolateral approach to the LV epicardium and placed tangentially in the myocardium. A 3.5 French active fixation lead was then advanced through the needle and fixated in the myocardium under CT visualization. He obtained good threshold and placement site in all pigs. No hematoma or tamponade was observed. When he used a perpendicular rather than tangential approach, tamponade developed.

A final area of interest is how the role of electrophysiology techniques such as registration of MRI or CT images with fluoroscopy, CARTO\textsuperscript{TM} (Cartomerge\textsuperscript{TM}, Biosense-Webster, Diamond Bar, CA, USA), or NavX\textsuperscript{TM} (St. Jude Medical, Minnetonka, MN, USA) could help identify the CS and coronary veins and improve navigation, improve clinical results, and decrease fluoroscopic exposure. This technique could also determine which branch or branches are present in a physiologically desirable area of the left ventricle. Finally, these tools may also determine whether a surgical approach would be preferable to a catheterization laboratory approach. There is little published data on the benefit of these techniques, but it is likely to be carefully studied in the future.

Many new methods are in development that will continue to make LV lead placement more successful and more precise. As we better understand where the best lead position is in

Figure 2. Stereotaxis map used to direct guidewire down a corkscrew-shaped vein. The lead was successfully implanted here.
different patients, it will become even more critical to obtain the desired lead site. As of yet, there are no controlled clinical trials to show the benefit of any of these new techniques. They could possibly prolong procedure time or increase operative risk. Future trials will allow for critical analysis rather than just observational benefit. Magnetic navigation and nontraditional approaches to access, however, have the potential to greatly increase successful lead implants at the ideal site.

References