

Practical Issues in Cardiac Resynchronization Therapy Device Implantation

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Cardiac resynchronization utilizes left ventricular (LV) pacing through electrodes inserted through the coronary sinus (CS) into LV veins to stimulate the LV myocardium. Successful insertion of LV pacing leads requires an understanding of the anatomic changes associated with cardiac remodeling and a combination of standard pacing and cardiac catheterization and interventional techniques. CS catheterization and venography identify and access the target LV vein for insertion of the pacing lead. Obtaining an adequate lead position involves reaching appropriate capture thresholds, avoiding extra-cardiac stimulation, and stabilizing the lead to avoid dislodgement. [Rev Cardiovasc Med. 2003;4(3):142-149]

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The implantation of left ventricular (LV) pacing leads to deliver cardiac resynchronization therapy (CRT) involves the following steps: obtaining venous access, inserting the right atrium (RA) and right ventricular (RV) leads, locating and entering the coronary sinus (CS), selecting a target LV vein, advancing the pacing lead to the targeted site, and removing the implant tools. To successfully implant LV pacing leads, the physician should have an in-depth understanding of the anatomy of the failing heart and the coronary veins and

be skilled in performing standard pacing lead insertion with techniques common to diagnostic cardiac catheterization and interventional cardiology. The combination of knowledge of cardiac anatomy, an understanding of the available diagnostic cardiac catheterization tools, and familiarity with maneuvers used in advancing catheters over guide wires allows the physician to safely and effectively provide CRT for patients with congestive heart failure (CHF) and conduction system disease.

CRT systems can be implanted using either right or left subclavian access, and each method has its advocates. At Emory Crawford Long Hospital, left shoulder access is preferred because it provides a more natural curve from the subclavian vein to the CS for the guiding catheters to follow. Access from the right subclavian presents a challenge because the guiding catheter must make two right-angle turns in opposite directions—one as it moves from the subclavian to the inferior vena cava and another as it moves from the RA to the CS ostium. However, right shoulder access provides a more comfortable position for the physician to utilize left anterior oblique fluoroscopic projection to help locate the CS. Venous access is obtained through insertion of a peripheral access line in a large arm or forearm vein on the side selected as the implantation site. Venous access for contrast injection helps to localize the subclavian vein during a difficult puncture. Performing a subclavian venogram before upgrading an existing system to CRT through addition of an LV lead can detect asymptomatic subclavian vein thrombosis, which presents in 10%–15% of patients with chronically implanted pacing leads.

Commercially available CRT

devices use an RA pacing lead and RV pacing or defibrillating/pacing lead system in conjunction with an LV lead. Inserting the RV lead before entering the CS provides a mechanism for emergency RV pacing should instrumentation with a guiding catheter inadvertently traumatize the right bundle branch during attempts to enter the CS. Patients who receive CRT should have underlying LV conduction system disease. Trauma to the right bundle branch may produce high-degree atrioventricular block and compromise patients with LV dysfunction. Therefore, the physician should obtain venous access for three pacing leads in the subclavian or cephalic veins. Insertion of the RV and RA leads should precede insertion of the LV guiding catheter/delivery system. After securing the RA and RV leads, connecting the RV lead to a temporary demand pacing generator provides pacing support in case of atrial-ventricular blockage. One can then safely proceed with CS catheterization.

An in-depth understanding of the anatomic changes of the failing heart increases the likelihood of successful CS entry. Right atrial enlargement, upward rotation of the long axis of the heart, posterior rotation of the short axis, and the increasing diameter of the mitral annulus combine to change the position of the CS ostium relative to the typical fluoroscopic landmarks used to identify cardiac structures during cardiac procedures.¹ An exaggerated Eustachian ridge or enlarged sub-Eustachian space within the RA creates a physical barrier to CS entry. Strictures, tortuous segments, and valves within the CS and its tributaries prevent catheters and guide wires from advancing to desirable locations that allow positioning of leads into target veins. Reviewing the echocar-

diogram before the implantation procedure can alert the physician to unusual RA enlargement or anatomy. Brief fluoroscopic inspection of the cardiac silhouette at the start of the implantation can help identify the degree of cardiomegaly or cardiac rotation and the presence of anatomic markers, such as right coronary artery calcifications or the lucent adipose pad marking the atrial-ventricular groove, which can help target the CS site of entry. Small volume injections of contrast material from the tip of the guiding catheter may help identify the CS ostium. However, the cumulative effect of contrast “puffing” can introduce potentially nephrotoxic doses to a patient with compromised cardiac output. A review of cardiac cineangiograms that were performed before the implantation procedure can provide a general guide as to the positioning of the CS in the RA. Visualization of contrast entering the atrium during the levo-phase after coronary injection can help locate the CS.

Catheterization of the CS

Successful catheterization of the CS involves entry from the inferior aspect of the RA, with the guiding catheter directed upwardly and posterior to locate the ostium. Entering the CS with a shallow-curve guiding catheter while approaching the ostium from above is rarely successful (Figure 1). Manipulation of preformed guiding catheters with tips curved to varying degrees may help to locate the CS ostium. Counterclockwise rotation of the preshaped guiding catheter directs it posterior in the atrium. If the guiding catheter enters the RV, withdrawal while applying counterclockwise pressure should cause the catheter to take the desired approach to the CS ostium. Remodeling of the RA

interferes with successful CS cannulation. If standard maneuvers with the preformed guiding catheters fail to locate the CS ostium, diagnostic coronary catheters inserted into the guiding catheters can provide additional three-dimensional flexibility to locate the CS (Figure 2). A multipurpose (MP A2), left internal mammary artery (LIMA), or Amplatz (AL-3) catheter can be inserted into commercially available CS guiding catheters to help reach the CS in markedly abnormal right atria. Alternative approaches to locate the CS ostium include manipulation of deflectable electrophysiology mapping catheters within the guiding catheter and intracardiac electrograms to identify the CS ostium. If the physician has difficulty locating the ostium, left coronary angiography during the implantation procedure can provide a guide to the OS. Intracardiac ultra-

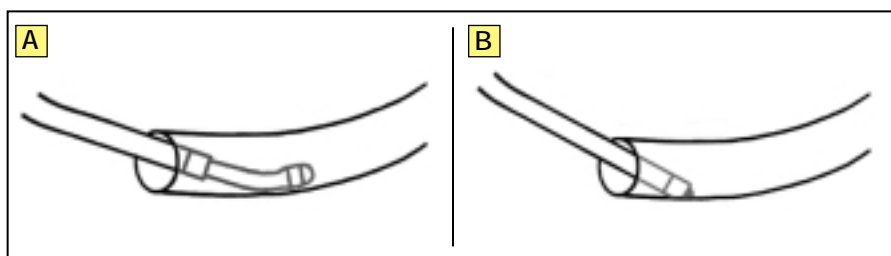


Figure 1. (A) The preferred approach for entering the coronary sinus (CS) involves advancing a guide catheter up and posteriorly from the floor of the right atrium. (B) Attempts to enter the CS from above will point the catheter into the inferior CS wall and prevent it from taking a coaxial position within the CS.

sound can also help to locate the CS ostium. However, one should use these modalities judiciously. If after numerous attempts with guiding catheters, deflectable electrophysiology catheters, or telescoping catheter-within-a-catheter techniques, the ostium cannot be visualized or entered, another attempt on a different day or by another physician may be prudent.

Once the guiding catheter engages

the CS ostium, advancing it 3–4 cm into the CS provides adequate stability for introduction of balloon venography catheters or pacing leads into the CS and cardiac veins (Figure 3). The guiding catheter should be advanced into the CS over a soft-tip guide wire (0.032–0.036 in. diameter) to reduce the likelihood of mural trauma. Loading a guide wire into the guiding catheter before inserting it into the central circulation not only provides a way to confirm that the guiding catheter has entered the CS by advancing the wire ahead of the catheter, but also provides a guide for seating the catheter within the CS and reducing the risk of dissection. Once the guiding catheter sits 3–4 cm within the CS, one can remove the guide wire and advance the balloon-tip catheter into position for contrast venography. Should valves within the CS prevent advancement of the guiding catheter, crossing the valve with the guide wire may open the valve and allow catheter advancement without damage to the valve and potential dissection. A guide wire (0.025 in.) can also be passed through the balloon catheter deep into the CS to safely advance the balloon catheter across strictures, curves, or valves in the CS.

LV Lead Placement

Retrograde injection of contrast material into the coronary venous



Figure 2. (A) Three 6-French diagnostic coronary angiography catheters that can be inserted into a coronary sinus (CS) guiding catheter to increase the ability to enter the CS ostium. From above to below: Amplatz-3, Multipurpose A2, and LIMA curves. (B) A Multipurpose A2 catheter inserted into a Medtronic MB-2 guiding catheter to access a CS ostium in an enlarged right atrium. (C) An Amplatz-3 diagnostic catheter inserted into a Medtronic MB-2 guiding catheter.

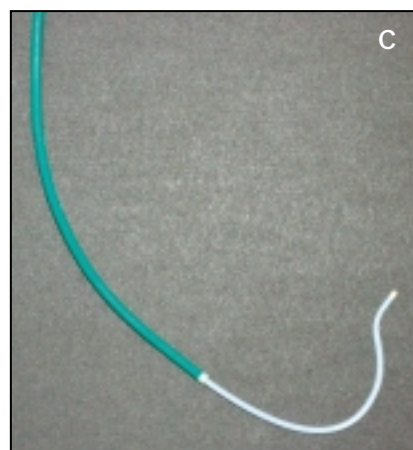
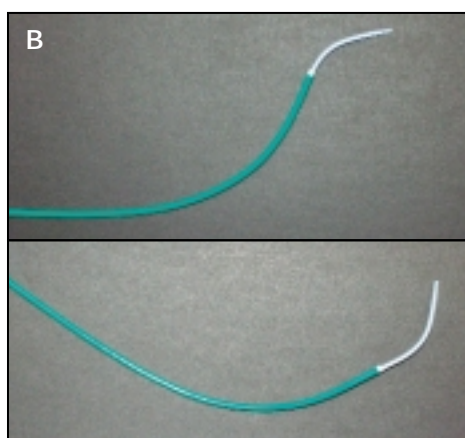




Figure 3. Advancing the catheter 3–4 cm into the coronary sinus provides a stable platform for the venogram catheter and allows advancement of the pacing lead into a coronary vein.

system opacifies all potential target veins, valves, strictures, collateral connections, and specific anatomic details that permit optimal placement of LV pacing leads (Figure 4). Balloon inflation within the CS blocks antegrade blood flow, and permits adequate opacification of the entire venous tree by retrograde filling of contrast through collateral venous channels. Low-pressure injection of diluted (50% saline) non-ionic

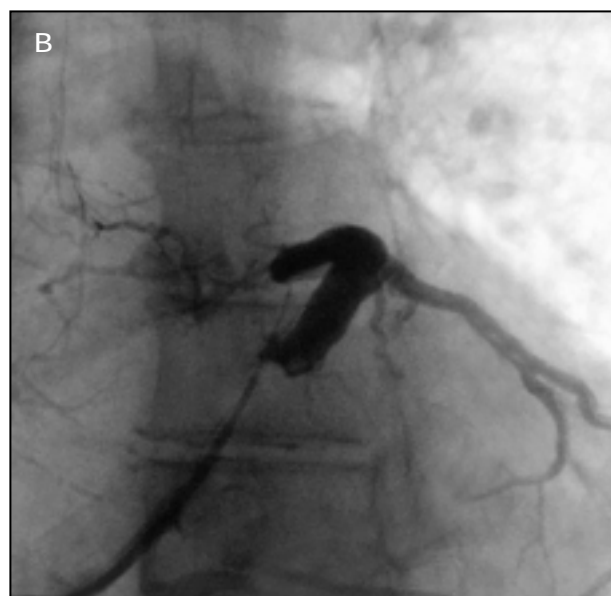
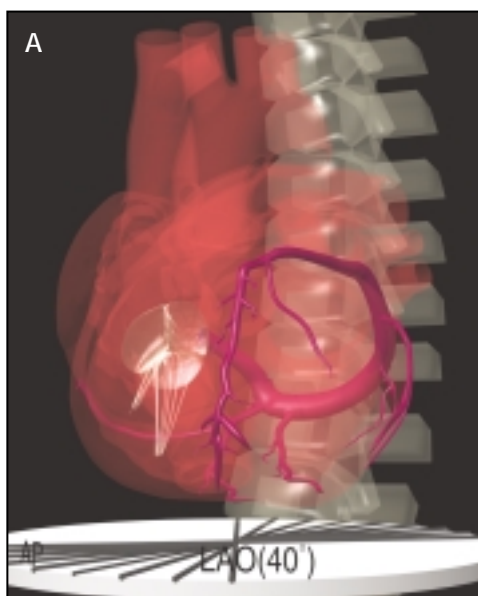
contrast material reduces the chance of vascular trauma, contrast nephropathy, and excessive osmolar loads in patients with CHF. Digitally acquired and stored images in two radiographic planes (anteroposterior/left anterior oblique or right anterior oblique/left anterior oblique) provide the optimal anatomic roadmap for advancement of guide wires and pacing leads into the targeted LV site. Good venographic technique not only demonstrates all possible cardiac venous targets but also can delineate the site of venous entry into the CS to allow proper steering of the guide wire and pacing lead into the selected vein. Venography to guide LV lead implant is not necessary for a successful implant; however, the advantages of proper venography greatly outweigh its risk to the patient.

Venous tributaries of the CS that drain the free-wall of the LV provide the ideal conduit for LV pacing lead insertion. Leaving a pacing lead within the anterior cardiac vein or the posterior intraventricular vein does not provide effective CRT

because the LV lead primarily stimulates the septum, with a delay before the wavefront reaches the lateral LV wall.² Inserting LV pacing leads such that the pacing electrode sits within the lateral, posterolateral, or anterolateral cardiac vein provides optimal CRT. Physicians have a choice of large-diameter, stylet-driven leads or smaller-diameter, over-the-wire leads for LV venous pacing. At Emory Crawford Long Hospital, over-the-wire leads are used in more than 90% of the cases; stylet-driven leads are reserved for large LV veins in which smaller, over-the-wire leads cannot be stabilized, posing an increased risk of lead dislodgement. The preferred approach to advancing stylet-driven leads involves bending the distal 1–2 cm of the stylet at an angle that corresponds to the angle of entry of the target LV vein into the CS. Bending the stylet allows for steering of the lead tip into the desired vein. Once the lead is in the tributary vein, placing a soft, straight stylet allows advancement of the lead to the desired position.

The over-the-wire technique allows

Figure 4. Veins that drain the lateral wall provide the ideal position for left ventricular (LV) pacing and cardiac resynchronization. The lateral, anterolateral, and posterolateral LV veins provide the best location for delivering cardiac resynchronization therapy. (A) Computer-rendered model of cardiac veins. (B) Venogram of similar view.



the physician to target the ideal cardiac vein and manipulate the lead into a second-order tributary to achieve optimal lead stability, avoid stimulation of the left phrenic nerve, and provide CRT. The physician should load a guide wire (0.014 in., intermediate or middle weight) into the lead and then bend the distal 3 mm of the wire (40°–60°) after inserting it through the lead. Inserting the lead and wire into the

positioning along the LV free-wall; maximal RV to LV electrode separation; stimulation at an LV site with the latest local activation, where a local electrogram falls in the most distal part of the surface QRS complex on electrocardiogram; absence of phrenic nerve stimulation; and a stable lead position. Data from numerous clinical trials of CRT systems have not been able to determine which segment of the free-wall

sitioning of the LV lead. Often, when a patient sits or stands after the procedure, the diaphragmatic threshold drops and even intermittent stimulation becomes unacceptable. Persistent diaphragmatic stimulation requires lead repositioning. Correcting the problem during the initial implantation procedure reduces the need for a subsequent operation.

Once the RA and ventricular leads are in place and secure, the implant delivery system should be removed. Techniques for removing the guiding catheter from the CS include longitudinal slitting of the catheter; removal of the catheter over the lead, while stabilizing the lead by inserting into it a relatively stiff wire; and breakage and peeling away of a catheter scored along its longitudinal axis. Advancement of the lead during removal of the guiding catheter will introduce redundancy of the lead into the venous system and dislodge its tip. Unintended advancement of the lead can occur during slitting if the physician pushes the slitting tool forward, instead of fixing it in space and drawing the guiding catheter into the blade. Advancing the “finishing wire” within a lead also pushes the lead forward. If the lead tip reaches a “dead-end” within the target vein, either of these maneuvers introduces excessive lead into the patient. Pushing the lead into the subclavian vein and pulling the peel-away guiding catheter out of the patient may produce the same effect. Excess lead slack, particularly in the RA, prolapses the lead into the RV and dislodges its tip. Tightly securing the sewing collars after removal of the stylet or finishing wire from the LV lead should prevent further dislodgement.

Troubleshooting

The leading causes of failed LV lead

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guiding catheter allows for advancement of the guide wire ahead of the lead and advancement of the combined system out of the guiding catheter. Rotation of the guide-wire tip steers it into a desired tributary vein while referring to the stored venogram for anatomic guidance. Once the guide wire enters the targeted vein, its advancement into the distal segment of the vein provides stability for the lead to track over the wire into the vein to reach the desired position for the pacing electrode. Advancing the lead while retracting the wire (the “push-pull” technique) helps to stabilize lead position by wedging its tip into small caliber vessels. Inserting the wire into second-order tributary veins moves the electrode tip away from a large caliber vein that may otherwise not afford the lead the desired stability. The over-the-wire technique also permits movement of the pacing electrode to multiple sites within one vein and allows for easy selection of alternate veins should one encounter unacceptably high stimulation thresholds or extracardiac stimulation during LV pacing.

The criteria used to identify an ideal LV pacing site include anatomic

(lateral, anterolateral, posterolateral, or apical) provides the greatest hemodynamic benefit.³ Acceptable LV stimulation thresholds vary from what is commonly accepted for RV and atrial stimulation. The physician may readily accept thresholds of up to 3 V at 0.5 milliseconds pulse duration in order to deliver CRT to a patient with CHF. When encountering a high stimulation threshold at an otherwise desirable anatomic LV lead position, the threshold should be measured at a variety of pulse duration settings (0.5–1.5 ms) to generate a strength/duration curve for the LV. Often, LV pacing at a higher pulse width lowers capture threshold to within an acceptable range of pulse generator energy output. The trade-off between successful LV pacing and decreased pulse generator duration should favor delivery of therapy to the patient who responds to CRT over concerns for pulse generator duration. Stimulation of the phrenic nerve as it courses along the lateral wall of the heart produces diaphragmatic stimulation during LV pacing. Intermittent diaphragmatic stimulation, even at high outputs, during lead testing should encourage repo-

implantation include inability to locate the CS ostium or advance the guiding catheter to a stable position and poor LV vein anatomy. Persistent phrenic nerve stimulation, CS dissection or perforation, and unacceptable stimulation thresholds lead to failure less often. Table 1 lists the causes of failed implant in a group of large CRT clinical trials.

Cardiac remodeling associated with LV systolic dysfunction creates anatomic challenges and can prevent insertion of the guiding catheter into the CS ostium. When remodeling occurs, the CS ostium moves to a relatively low and posterior position. The angle of approach into the CS changes as the atrial-ventricular groove assumes a more vertical orientation. If numerous attempts to locate the CS with standard guiding catheters fail, the physician should consider use of additional diagnostic catheters to locate the ostium. Inserting a diagnostic catheter into the guiding catheter creates a telescoping catheter system with increased reach and rotational capability to locate the CS ostium. In the greatly enlarged RA, an AL-3 catheter inserted into a conventional guiding catheter extends the reach of the

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system and directs a guide wire or contrast injection superiorly toward an upwardly angulated CS. The MP-A2 extends the reach of the delivery system with less angle and provides the versatility to point up or down at the end of the guiding catheter. Inserting a LIMA catheter into a guiding catheter facilitates entry into a downward-directed CS ostium or into a posterior intraventricular

vein. Once in the CS, the telescoping diagnostic catheter can track over a guide wire and provide a stiffer path over which the guiding catheter can advance to a more stable CS position. Pulling the guide wire or diagnostic catheter back while simultaneously advancing the guiding catheter facilitates tracking of the guiding catheter. Use of a steerable electrophysiology catheter provides a less versatile option to the telescoping catheter technique at a greater

expense. The stiff EP catheter may traumatize the CS because it cannot advance over a wire, and one cannot inject contrast through it.

Once inside the CS, barriers to successful advancement of guide wires and leads into the target veins include severe angles at which veins enter the CS, tortuous segments within the veins, and the caliber of the veins themselves. Proper shaping

of the guide-wire tip, adequate guiding catheter support of the lead/wire system, and venograms that define venous entry into the CS provide the best chance of successful over-the-wire lead advancement. When a vein enters the CS at a highly acute angle ($> 120^\circ$), the guide wire may have difficulty entering it or may be unable to advance to a distal stable site, or the lead may not track across the acute angle and may dislodge the wire. When veins enter the CS at acute angles, the following approach can be taken: Insert a 6-French LIMA into a guiding catheter positioned in the CS beyond the target vein, and use the distal hook of the LIMA catheter to engage the vein by pulling the LIMA catheter back to the insertion point. Once the vein is engaged (confirmed by contrast injection), pass a heavy-weight angioplasty wire through the LIMA into the most distal segment of the target vein. Remove the LIMA, leaving the guide wire in place. The heavyweight wire will help to straighten the angle and curves of the vein. "Backload" a previously prepared lead through the wire and

Table 1
The Multicenter InSync Randomized Clinical Evaluation:
Reasons for Unsuccessful Lead Placement

Reason	No. of Cases
Unable to access coronary vein	14
Unable to obtain distal location	13
Dislodgement/unstable position of LV lead	10
Elevated LV pacing threshold	4
Cardiac vein vessel too small	2
Phrenic nerve stimulation	1
Inadequate sensing	1
Heart block	1

Total of 43 patients unsuccessfully implanted. Reasons for failure are not mutually exclusive.

into the target vein. This technique requires that the physician fix the guide wire in space to prevent advancement of the wire during lead progression. Pushing the wire into the vein will dislodge the guiding catheter from the CS. Only quick removal of the excess guide wire (and sometimes the LV lead as well) will reseal the guiding catheter in the proper position. The common reflex response is to try to advance the guiding catheter into the CS; however, this will dislodge the catheter, LV lead, and guide wire.

In some patients, coronary venograms may demonstrate an apparent absence of veins draining the LV free-wall or show only small-caliber veins that cannot accept even a 4-French diameter pacing lead. Careful analysis of the venogram often shows a large posterior interventricular vein with a large tributary that parallels the CS and drains the LV lateral wall. Injection of contrast well into the CS during balloon occlusion will demonstrate this venous drainage during delayed venous flow via collaterals from the anterior/great cardiac vein to the lateral veins. Identification of the entry point of the posterior vein into the CS facilitates advancement of the guiding catheter into the large vein for passage of the guide wire and leads to a desirable lateral tributary. Use of the LIMA within the guiding catheter, with the LIMA pointing to the posterior vein, often provides the best approach to entering this potentially implantation-salvaging vein.

Use of heavyweight guide wires, telescoping diagnostic catheters, and proper venogram technique will produce excellent results in most cases. Venous strictures and veins of inadequate caliber may respond to balloon venoplasty techniques and allow for successful introduction of

LV leads.⁴ At Emory University, we have implanted more than 900 CRT devices. Our overall success rate of transvenous LV lead implantations exceeds 93%, with a 96% success rate over the past 2 years, after the adoption of the over-the-wire approach. We have used venoplasty in three cases. An implanting cardiologist with experience using inter-

When hypotension occurs in the setting of suspected perforation, immediate echocardiography can define the need for intervention with administration of fluids, vasopressors, or pericardial drainage.

ventional techniques may view venoplasty as another tool to approach difficult cases. However, the need for resorting to venoplasty to achieve success has not been fully determined in controlled studies. An evaluation of the extraordinary measures used to achieve successful LV lead implantation needs to consider the incremental cost of equipment and the potential hazard to the patient. Some transvenous LV implants will fail.

The complications associated with LV lead implantation include CS dissection, vein perforation, LV lead dislodgement, and device-associated complications resulting from integration of additional leads placed in cardiac chambers not previously sensed or paced. Although CS/venous trauma emerged as a new procedural complication associated with LV lead implantation, most perforations produce little, if any, clinical consequence.⁵ One should recognize when a catheter tip enters the subintimal space and, thus, avoid injecting large amounts of contrast to create a stain. Venous perforation usually does not produce hemodynamic instability because the CS blood circulates at low pressure and the pericardium contains the perfo-

ration. When hypotension occurs in the setting of suspected perforation, immediate echocardiography can define the need for intervention with administration of fluids, vasopressors, or pericardial drainage. In cases in which large contrast stains prevent proper visualization of cardiac venous anatomy or the CS is occluded, in the absence of hemo-

dynamic instability, repositioning the guiding catheter or pacing lead into the proper position usually allows one to continue the implantation procedure. Should injection of contrast stain create a large stain or should a dissection occlude the CS, the implantation procedure should be aborted and another attempt should be considered, after a delay of at least two weeks to allow the injury or stain to resolve.

Dislodgement of the LV lead after successful implantation eliminates the beneficial response to CRT. Data from CRT trials indicate that lead dislodgement rates approach 10%. If a patient has recurrent symptoms of CHF after a CRT device implant, evaluating capture thresholds may reveal loss of capture as the cause. Chest radiographs may confirm movement of the LV lead from its original site. However, micro-dislodgement of the lead may produce loss of capture without the appearance of obvious changes in the chest x-ray. Successful repositioning of dislodged LV leads usually requires reinsertion of the guiding catheter to provide enough support for advancement of either stylet-directed or over-the-wire leads. One may attempt to advance the lead over

a guide wire or by inserting a stylet without the use of a guiding catheter. Failure to quickly move the lead to a desired position calls for the insertion of a new guiding catheter. Inserting a heavyweight guide wire (0.014–0.018 in.) into the lumen of a dislodged over-the-wire lead will create vascular access over which to place subclavian introducers and even a new guiding catheter. If removal of the chronically implanted lead does not dislodge the guide wire from the CS, careful insertion of the guiding catheter-introducer combination over the guide wire may allow tracking of the guiding catheter directly into the CS. Removal of the introducer then allows backloading of the new LV pacing lead. If one cannot preserve the guide-wire position within the CS, insertion of the heavy guide wire into the lumen of the dislodged lead at least provides central venous access without the need to repeat the subclavian puncture. The physician should consider

what factors contributed to the dislodgement of the original lead when choosing a site for the new lead. Avoiding a mismatch in lead-vein size, proximal lead positions, excessive slack in the lead, and prolonged observation to detect early lead instability in the new position may decrease the probability of repeat dislodgement.

Conclusion

Successful delivery of CRT requires a technique that safely implants pacing leads into a LV free-wall vein for biventricular stimulation. Understanding the anatomy of the failing heart allows the implanter to overcome most of the hurdles complicating CS catheterization. The technological improvements in delivery system and LV pacing lead design provide tools to advance pacing leads to desired positions along the LV free-wall. Early recognition of potential complications increases the safety of the implantation pro-

cedure and allows the physician to take remedial action to correct problems that may decrease the efficacy of CRT. ■

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Main Points

- To successfully implant left ventricular (LV) pacing leads, the physician should have an in-depth understanding of the anatomy of the failing heart and the coronary veins and be skilled in performing standard pacing lead insertion with techniques common to diagnostic cardiac catheterization and interventional cardiology.
- In the failing heart, right atrial enlargement, upward rotation of the long axis of the heart, posterior rotation of the short axis, and the increasing diameter of the mitral annulus combine to change the position of the coronary sinus (CS) ostium relative to the typical fluoroscopic landmarks used to identify cardiac structures during cardiac procedures.
- If standard maneuvers with the preformed guiding catheters fail to locate the CS ostium, diagnostic coronary catheters inserted into the guiding catheters can provide additional three-dimensional flexibility to locate the CS.
- Retrograde injection of contrast material into the coronary venous system opacifies all potential target veins, valves, strictures, collateral connections, and specific anatomic details that permit optimal placement of LV pacing leads.
- Inserting LV pacing leads such that the pacing electrode sits within the lateral, posterolateral, or anterolateral cardiac vein provides optimal cardiac resynchronization therapy (CRT).
- The over-the-wire technique provides the physician with the ability to target the ideal cardiac vein and manipulate the lead into a second-order tributary to achieve optimal lead stability, avoid stimulation of the left phrenic nerve, and provide CRT.
- Successful repositioning of dislodged LV leads usually requires reinsertion of the guiding catheter to provide enough support for advancement of either stylet-directed or over-the-wire leads.