Implementing Cardiac Resynchronization Therapy in Routine Clinical Practice: Preoperative Considerations and Implantation Techniques

Herbert Nägele, MD,* Maria Angeles Castel, MD†

*St. Adolfstift Medical Clinic, Reinbek, Germany; †The Thorax Institute, Hospital Clinic, University of Barcelona, Barcelona, Spain

Cardiac resynchronization therapy (CRT) using coronary sinus (CS) leads is an established therapy for congestive heart failure in patients with asynchronous ventricular contractions. CRT improves not only exercise tolerance but also the patient's prognosis. Appropriate patient selection for CRT is essential for a successful therapeutic response. Inclusion criteria are based on symptoms (New York Heart Association classes III and IV), a reduced ejection fraction, and a widened QRS complex. The presence of objective markers of heart failure can be considered a prerequisite for successful CRT. CRT procedures are much longer than regular pacemaker implantations, and thus the risk of infection may be greater. Successful therapy depends on the placement of left ventricular leads, usually via the CS, which is a technically more challenging procedure than regular pacemaker implantations. Complications specific to CRT include ventricular arrhythmia, such as ventricular tachycardia or ventricular fibrillation; total atrioventricular block or sinus arrest without any escape rhythm; and CS dissection.
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Key words: Cardiac resynchronization therapy • Coronary sinus leads • Congestive heart failure • Left ventricular leads

Cardiac resynchronization therapy (CRT) using coronary sinus (CS) leads is a new stimulation method for the therapy of patients with congestive heart failure (CHF) and interventricular and intraventricular conduction delays resulting in asynchronous ventricular contractions. The ability of this therapy to augment cardiac hemodynamics is now well characterized.[1] Recently, it has been shown that CRT improves not only exercise tolerance but even the patient's prognosis.[2,3] More and more patients with an indication for

this therapy are being identified, and many cardiac centers are rapidly adopting this implantation method. In 2006, 28,700 CRT systems were implanted in Western Europe.[4] However, the procedure is more complex than for regular pacemaker implantation, and therefore detailed information on preoperative preparations and implantation techniques is of great importance. This article will review preoperative considerations and CS lead implantation methods.

Patient Selection

Selecting the right patient for CRT is an absolute prerequisite for a successful therapeutic response. Guidelines published by the European Society of Cardiology in 2007[5] favor relatively liberal inclusion criteria based on symptoms (New York Heart Association stages III and IV), a reduced ejection fraction (< 35%), and a widened QRS complex (> 150 ms for class I level of recommendation, and 120-150 ms for class II recommendation). Potential patients must be symptomatic despite optimal medical therapy, including β-blockers, angiotensin-converting enzyme (ACE) inhibitors or equivalents, and diuretics. QRS broadening may be due to a spontaneous block (class I level of recommendation) or chronic right ventricular stimulation (class II level of recommendation). There is lower evidence for a therapeutic effect in patients with shorter QRS durations (120-150 ms), resulting in a lower class of indication. However, when asynchrony can be documented—for example, by means of tissue Doppler examination—CRT may be as effective as in patients with broader QRS intervals. One could also argue that the presence of objective markers of heart failure is a prerequisite for successful CRT.

Although these criteria seem to be simple, things become more complicated in daily clinical practice. Dyspnea on exertion and fatigue can be caused by different mechanisms ranging from pulmonary disease to depression. With this in mind, we think that the determination of objective values, such as the brain natriuretic peptide (BNP) level, is a useful approach for the detection of conditions in addition to CHF. Indeed, a recent publication showed that nonresponders to CRT had significantly lower BNP levels than patients who were successfully treated with this method.[6] In other words, patients with normal BNP levels should be carefully investigated to identify whether they have a true indication. In addition to the previous methods, a cardiopulmonary exercise test is very useful in patient selection. It has been shown that patients with an oxygen uptake of more than 16 mL/min/kg will not profit from CRT, at least in the first 6 months.[7]

With the use of BNP and cardiopulmonary exercise testing, patients too healthy for CRT can be excluded from a therapy that would not improve their condition (however, a long-term beneficial effect has not been excluded). This does not mean that these patients do not need an implanted cardiac device, as they are still at risk from sudden cardiac death and may benefit from primary prophylaxis with an implanted defibrillator.[8] It raises the question of whether patients with a CRT indication should receive a device with simultaneous defibrillation capability. Despite information from randomized studies, the evidence is not very clear: data from the Comparison of Medical Therapy, Pacing, and Defibrillation in Heart Failure (COMPANION) study after 3 years and the Cardiac Resynchronization-Heart Failure (CARE-HF) trial (without defibrillators) both show a reduction in the incidence of sudden death.[2,3] Increasing numbers of patients currently in clinical practice are being treated with CRT devices with or without implantable cardioverter-defibrillators.[4] For young patients especially, it seems unfair to implant CRT-pacing devices only because they are threatened with lethal arrhythmia in the long run, despite an increase of the ejection fraction above the critical border of 35%.[9]

Preoperative Considerations

As outlined above, patients referred for CRT should be thoroughly screened for the etiology and characteristics of their heart failure—even twice, if necessary. Medical therapy should be optimized in regard to the kind and dosage of therapy. At least 3 standard drugs (β-blockers, ACE inhibitors, and diuretics) in their maximal possible doses should be administered before surgery. Interventions should be delayed if attempts at prior therapy were insufficient. Most importantly, patients should be informed that the device does not replace medical therapy but is an "add-on." Patients should not have other underlying conditions, such as uncontrolled malignancy, that may limit their life expectancy to less than 1 year. Patients and relatives should be thoroughly informed about the method, especially about possible complications, and about the occurrence of phrenic nerve stimulation (which is harmless but very uncomfortable for the patient). The concomitant use of a defibrillator should be discussed. Some patients, especially the elderly, appreciate the improvement in their quality of life, but would prefer a sudden death as opposed to a slow death from pump failure. Informed written consent should be obtained and standard information brochures distributed 24 hours before the procedure.

On the morning of the procedure, patients should take their heart failure medication without diuretics and with little water, to avoid or reduce decompensations during the procedure. Exposure to contrast media is significant (the mean volume of x-ray contrast agent in our experience is 45 mL ± 30 mL), so an acetylcysteine infusion may be of use preoperatively and postoperatively to reduce increases in creatinine levels, especially in the case of renal failure. Renal values should be checked at least once in the first 24 hours after the procedure.

Patients should have venous access contralateral to the implantation site, which will be on the left in most cases because defibrillation thresholds are lower due to greater inclusion of the heart in the electrical field. To treat malignant ventricular arrhythmia induced by manipulation in the area of the tricuspid valve, defibrillation patches should be applied in typical positions over the chest wall and connected to a bipolar defibrillator. Patients should be monitored continuously with an electrocardiogram (ECG), pulse oximetry, and noninvasive blood pressure monitoring. Some centers prefer invasive arterial blood pressure monitoring, but in our experience, it is not routinely necessary. Similarly, many centers prefer to use general anesthesia, whereas we recommend local anesthesia plus intravenous sedation with midazolam and propofol as needed under background therapy with morphine. This approach allows for pocket preparation and shock testing with very limited circulatory alterations and good postoperative analgesia. We routinely use perioperative antibiotic prophylaxis.

It should be taken into account that CRT procedures are much longer than regular pacemaker implantations, and thus the risk of infection may be greater. Interventions should be performed without time pressure. Figure 1 shows that implantation time could reach 3 to 4 hours, even when performed by experienced physicians. (The mean operation time in our cohort was 110 min ± 35 min, and the mean fluoroscopy time was 15.8 min ± 11 min.) We found that more experience did not necessarily lead to shorter procedures. Clinicians with more experience may attempt to reach positions that are technically more difficult but hemodynamically better.

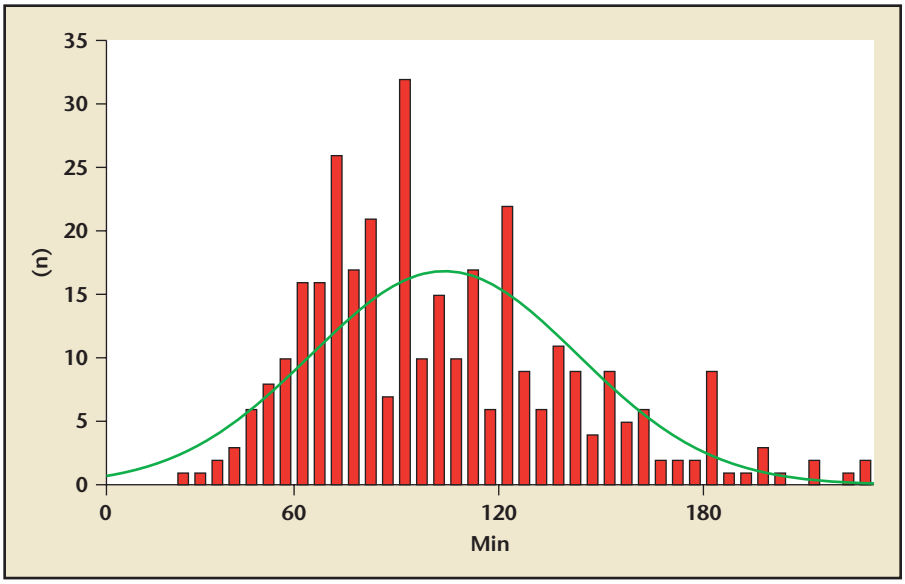

Figure 1. *Length of cardiac resynchronization implantation (in minutes) from incision to suture in 400 patients.*
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It is optimal to perform device implantations in a separate operating room that is reserved for these procedures. In our experience, anterior-posterior projections are sufficient for successful implantations, thus avoiding the need for invasive catheterization laboratories, which have been under economic pressure to produce high numbers of interventions and may be needed for patients presenting with an acute myocardial infarction. During the procedure, the patient and clinicians should be protected from x-ray exposure by following appropriate standard procedures, including the use of lead glasses (Figure 2).

Venous Access

We prefer puncture of the subclavian vein over the cephalic vein in CHF patients for several reasons. First, to pass 3 leads, including a thicker defibrillator lead, via the cephalic veins may not be an easy task. Second, due to the congestive state of CHF patients, venous filling is much better, which makes subclavian puncture very easy. We prefer a single puncture and consecutive passage of 3 Seldinger wires over 1 introducer sheath. These wires should be fixed securely to avoid intravascular dislocation. Nevertheless, the approximate 1% risk of pneumothorax must be discussed with the patient preoperatively.

Right Ventricular Lead Implantation

Right ventricular leads should be implanted first to allow the possibility of stimulation in the case of total

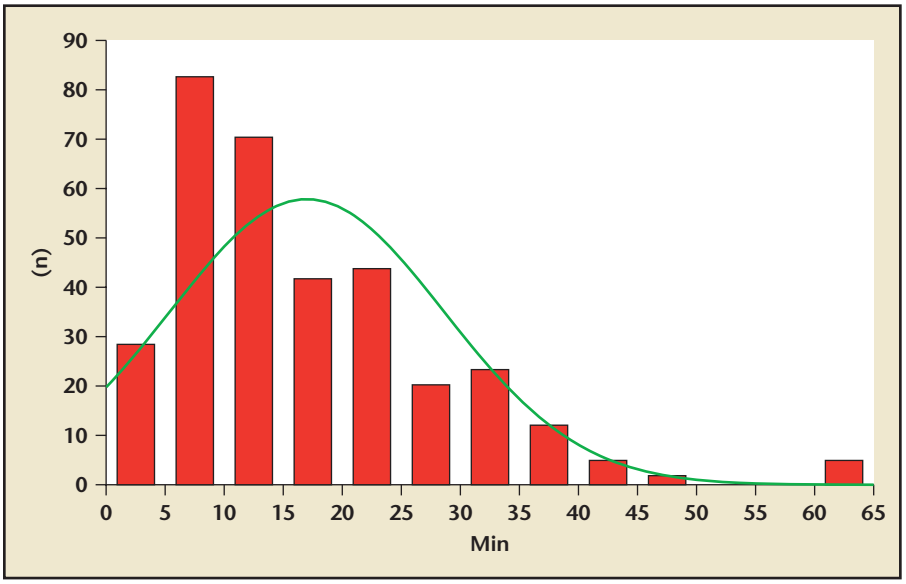

Figure 2. *Length of fluoroscopy times (in minutes) in cardiac resynchronization implantation procedures in 400 patients.* www.medreviews.com

atrioventricular (AV) block during manipulation of the CS ostium. This complication occurs at a rate of approximately 1%. Some patients may never regain AV conduction, even years after the procedure. Furthermore, it is helpful to know the level of the tricuspid valve, which can be easily extrapolated from the course of the ventricular lead.

CS Ostium Localization

Failure of the implantation procedure has been mostly due to an inability to locate the CS ostium.[10] Therefore, every effort should be made to overcome this serious hindrance. Some centers prefer to make a venous angiogram of the CS preoperatively, for example, via the femoral veins. Clearly this step helps a little, but one still must cannulate the CS ostium coming from another access site and using other angulations. Sometimes it may be helpful to review a coronary angiogram of the patient in detail because the late venous phase may uncover at least the main stem of the CS, showing its drainage site in the right atrium.

Data from cardiovascular computed tomography or magnetic resonance imaging can also be useful in selected cases, although they are rarely used in clinical practice due to their high costs. Whether the use of fiber-optic catheters will be useful for optical visualization of the CS entrance must also be shown in further studies.[11]

The ostium of the CS can be localized in different ways, such as:

- Direct intubation with standard application sheaths of different shapes (with some risk of CS dissection, the sheaths have to be turned counterclockwise at the level of the tricuspid valve, avoiding rhythm disturbances).
- Localization with deflectable catheters (electrophysiologic study catheters).
- Cannulation with guidewires.
- Cannulation with indwelling catheters (multipurpose).

In most cases, the CS ostium will be located posterior at the level of the tricuspid valve. However, there are many variants with higher or lower ostium localizations, and even the ostium and the CS main stem may vary in diameter from 4 mm to 30 mm. Its angulation in the frontal plane and deviation from the center line may also vary. In addition, very steep angulations are possible, as pipe-like structures including valves and membranes sometime make ostium localization a difficult task. Also, venospasm is a possibility, making intubation possible only after application of nitroglycerine.[12] Furthermore, all sheaths must be flushed regularly with heparinized saline to avoid clotting and possible thromboembolic events.

Selection and Cannulation of Target Veins

The anatomy of the CS and its side branches shows great variation among individuals, making visualization mandatory in every case. The selection of a target vein should be done by means of a retrograde venous angiography using standard balloon catheters, allowing temporal blockade of the venous return of the CS. Data from Meisel and colleagues[13] show that the use of correct visualization techniques allows a suitable target vein to be identified in 99% of patients. Care should be taken to avoid making the suitable veins invisible by covering them with the balloon or by making the angiography too distal (Figure 3). Early vein branches could be visualized by longer injections to uncover collateral flow to other venous regions. Different injections may be necessary to visualize all regions of interest. Optimally, CS leads should be placed in the regions with the latest activations. These are mostly posterolateral or anterolateral veins. The site of the latest activation could be detected by comparing intracardiac electrograms to the surface ECG. Sensing the left ventricular (LV) late in the course of the surface ECG indicates an acceptable position. Some

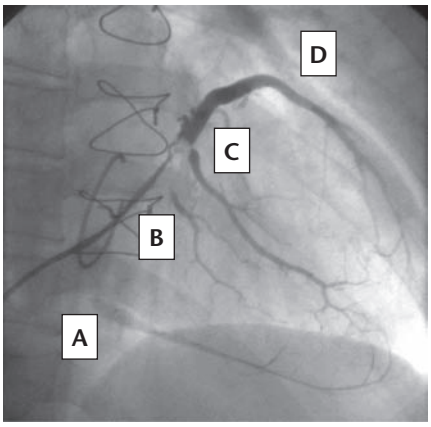

Figure 3. *Retrograde coronary sinus angiography. Retrograde visualization of a posterior vein* **(A)**. *Weak visualization of an early posterolateral vein proximal to the balloon* **(B)**. *Visualization of a suitable posterolateral vein despite close contact of the side branch and balloon* **(C)**. *Good visualization of the anterior vein* **(D)** *(a second choice for coronary sinus lead implantation because it is not in the region of the latest myocardial activation).* www.medreviews.com

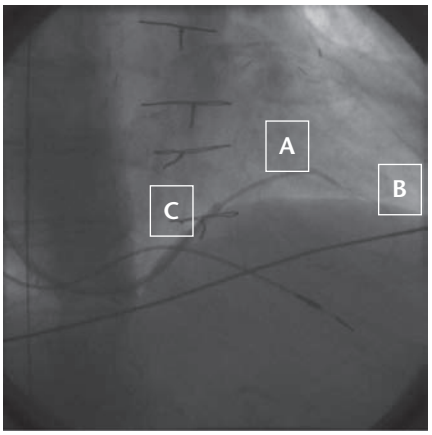

Figure 4. *Cannulation of a posterolateral coronary sinus side branch with the help of a conventional 5F Judkins right catheter* **(A)**. *A small percutaneous transluminal coronary angioplasty guidewire* **(B)** *was advanced via this catheter, the introducer sheath* **(C)** *was removed, and the lead was placed easily using the so-called over-the-wire technique.* www.medreviews.com

centers perform intraoperative measurements at different lead positions using pressure volume loops obtained by the use of Millar pressure catheters (Millar Instruments, Inc., Houston, TX) in the left ventricle.[1] However, up to now, no data have conclusively shown that the rate of nonresponders could be reduced by this invasive, time-consuming, and expensive method.

In our series of patients, CS leads were positioned as follows: 51% in posterolateral veins, 38% in anterolateral veins, and only 11% in anterior veins.[10] Visual selection of the right position is the most important measure to encourage an adequate response. In our series, only 58% of the patients with anterior leads were responders, in contrast to 91% of patients who had anterolateral and posterolateral CS leads.[14]

Once a target vein is identified, a method should be chosen for its cannulation. This can be done with the lead itself, by using the preshaped lead body, which can be exposed by different indwelling wire positions. If the target vein cannot be reached directly, an attempt should be made to intubate the branch with a percutaneous transluminal coronary angioplasty (PTCA) wire using a "torque" technique as in a conventional interventional coronary procedure. The lead can be advanced by retrograde introduction of the wire in the tip of the lead. If the side branch cannot be reached by the lead or wire, then special thin, indwelling catheters (a 5F Judkins right coronary catheter [Figure 4] [Cordis Europa, Roden, Holland] or another specially designed catheter with an angulated or hockey-stick tip) can be used, and the wire can be applied via this route. Great care must be taken that the guiding catheter is not pushed outside the CS ostium, and, therefore, it should be advanced as much as possible inside just before the side branch. When it is not possible to advance the guiding catheter enough, it may be feasible to add a stiffer electrophysiologic study catheter.

CS Lead Implantation and Fixation

The CS lead type should be selected according to vein anatomy *after* retrograde angiography. For big veins, stiff bipolar leads with larger preshaped angulations should be chosen. For small veins, unipolar thin leads—even straight ones—may be more suitable. The availability of an over-the-wire lead is warranted in nearly every case, in our experience. Classically, CS leads must be pushed in a wedge position to yield a stable fixation. However, this goal cannot be met every time due to anatomic differences such as large venous diameters or phrenic nerve stimulation in very distal positions. However, the apparently simple solution of proximal lead positioning is a difficult task, resulting in a high number of dislocations and high stimulation thresholds despite preshaped angulations in commercially available leads. Active fixation may be an option in this difficult situation (Figure 5). Currently, 1 special model of an active CS lead is available using expandable tines. Our first experience with this lead showed no dislocations and low and stable thresholds, but difficulties with extraction.[15] In our experience, this lead makes other methods of lead fixation, such as the retained guidewire technique or fixation with stents, unnecessary.[16-18] This is especially true in regard to the retained guidewire technique, which could result in a fracture of the total CS lead body.[19] It has been recently proposed that small 4F screw-in leads are useful for LV stimulation,[20] but this approach must be supported by further safety studies. The risk of pericardial hemorrhage with this measure should be taken into account.

Magnetic navigation may be another "modern" technology to reach side branches in the case of difficult anatomic positioning.[21] However, this is an expensive procedure that will be available only in certain specialized centers in the near future. In regard to optimal thresholds or

Figure 5. *Schematic views of fixation mechanisms of different types of coronary sinus leads. Active lead fixation with retractable tines* **(A)**. *Passive lead fixation by preshaped lead body* **(B)**. *Passive lead fixation by lead wedging* **(C)**. www.medreviews.com

signals, stimulation thresholds up to 3 V or even 5 V may be acceptable in the case of a very good hemodynamic situation if no other options exist. It should be taken into account that thresholds may rise in the first 24 hours, especially when nonactive CS leads are used. Although signals are not very useful, high signals usually reflect low thresholds. In our series of patients, the mean signal in LV was 17 mV ± 10 mV, and the mean threshold in LV at 0.5 ms was 0.9 V ± 0.8 V.

Atrial Lead Implantation

To complete a CRT system, an atrial lead should be placed. We recommend implanting an atrial lead even in patients with long-lasting atrial fibrillation because rhythm normalization may occur during hemodynamic improvement. For better manipulation in the infraclavicular space in the presence of the guiding catheter, we routinely leave the introducer sheath in place during positioning.

Introducer Sheath Removal

The final step of CRT implantation is the removal of the introducer sheath, mostly with the use of slitter tools. Be aware that all your previous work can be destroyed within a second during this delicate procedure. It has not been proven that continuous fluoroscopic monitoring of the disaster improves these last critical moments, so refrain from it and just push. All that can be done is to stabilize the CS lead in its proximal region with an indwelling soft catheter.

Intraoperative Problems and Complications

A thorough knowledge of possible complications is needed to avoid adverse consequences and keep patients safe during the procedure. In addition to typical complications of device implantations, such as pneumothorax, bleeding, and infection, CRT-specific problems may occur.

Ventricular arrhythmia, such as ventricular tachycardia or ventricular fibrillation, may be induced by sheath manipulation. All of these patients have congestive heart failure, and many have infarct scars, which greatly enhances the electrical vulnerability of their hearts. In our experience, an external cardioversion and/or defibrillation has been necessary in about 2 out of 100 patients. Even a simple atrial flutter or atrial fibrillation will cause circulatory problems in patients with severely depressed ventricular function. Double check if the patient has been pretreated with a β-blocker, and consider intravenous application of amiodarone throughout the procedure to maintain electrical stability.

A second concern, as mentioned above, is total AV block or sinus arrest without any escape rhythm. Therefore, placement of a right ventricular lead is mandatory before one can proceed to CS ostium localization. In our experience, external stimulation via cutaneous patches is too insecure for successful antibradycardiac stimulation. This complication could also occur in 1% to 2% of interventions.

Another significant problem is CS dissection, which can occur at a rate of 2% to 6% and is characterized by visible contrast media paravasate beside the coronary vein system. However, the consequences of this situation have been limited to a reduced visualization of the CS stem and side branches, and, luckily, hematoma or pericardial effusions have rarely occurred. However, dissection of the membrane in some cases makes it very difficult to be crossed by sheaths or leads (Figure 6).

Rare events include perforation of the CS (in our series, occurring in 1 out of 500 cases), which can cause free flotation of the lead in the pericardial space. Hard push maneuvers should be avoided, especially at sites of angulation. One patient in our series experienced pericardial tamponade several days after the procedure, without overt perforation during the procedure. We suggest that silent inadvertent CS perforation can occur at any time with small guidewires, and we therefore recommend the performance of routine echocardiography the day after the procedure to rule out this complication. It should be noted that death during the procedure is a very rare event—for

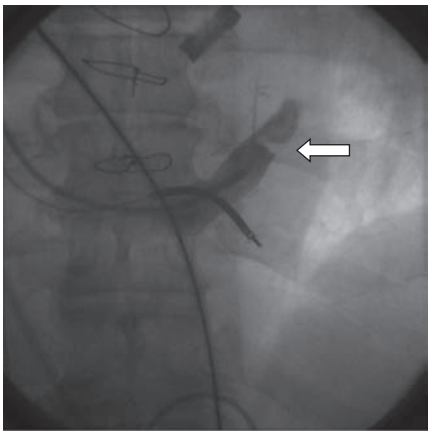

Figure 6. *Dissection membrane or valve (arrow) in the main stem of the coronary sinus, making cannulation very difficult. This barrier was finally passed with a deflectable electrophysiology catheter.*
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example, in the COMPANION trial, the mortality rate was 0.3%.[2] In our series, no patients have died during the procedure.

Postoperative Complications

A complication that requires reoperation is the early dislodgement of the CS lead (Figure 7, left image). It can occur in up to 10% of cases, especially with older and straight CS leads.[10] Dislocation numbers can be brought down to zero with the use of an active fixation method[15] (Figure 7, right image). In our series, early infections were observed in 2 patients within 3 weeks of the procedure. Both patients needed system explantation and new implantation several weeks later. Chronic infection is also possible; 2 patients in our series developed infections 1 and 3 years postoperatively. The infections were from *Streptococcus* (at 1 year) and *Corynebacterium* (at 3 years). Luckily, in both cases, removal of the CS leads was easily performed, even after the device had been implanted for years. Fortunately, these patients had no active fixation. Therefore, infection may occur at a total incidence of 1%, more frequently than in regular pacemaker procedures,[22,23] due to longer operation times and despite the use of perioperative antibiotic prophylaxis.

Loss of function in the CS leads has occurred up to 18 months after implantation. After 2 years, 85% of initial implantations could be classified as long-term functioning. Late CS lead reoperations were necessary in up to 5% of cases. Reasons for late reoperations were phrenic nerve stimulation and chronic exit block. Interestingly, this demonstrates that nontolerable phrenic nerve stimulation sometimes occurred despite intense intraoperative mapping and high voltage stimulation. It has to be emphasized that testing in a flat position does not rule out later phrenic nerve stimulation in other body positions (eg, lying on the right or left side). If possible, avoidance of the lateral positions for implantation will reduce the incidence of phrenic stimulation, but at the cost of possible higher dislocation rates. Both problems could be solved by means of active CS lead fixation.[15] Phrenic nerve stimulation can also be corrected by electronic repositioning—eg, changing the pacing polarity (if the implanted CS lead is bipolar and the implanted device has this feature).

Proarrhythmia is another possible effect of CRT, although the association is not yet well-characterized. In 2003, Medina-Ravell and colleagues[24] described a patient who developed torsade de pointes (TdP) tachycardia after implementation of biventricular stimulation. Data from patient studies and animal experiments suggest that biventricular stimulation via the epicardium may alter the transmural sequence of activation and can therefore induce TdP in a subset of patients. In our series, we also observed 4 patients who had newly developed VTs during the first 24 hours of implantation. Three of them were treated successfully with defibrillator shocks; the fourth patient, who had only an antibradycardiac system, was found dead in the morning. Pacemaker data stores revealed ventricular tachycardia corresponding to the time of death. Based on this experience, we would recommend continuous ECG surveillance for at least 25 hours after the procedure, especially in patients who have only pacemakers.

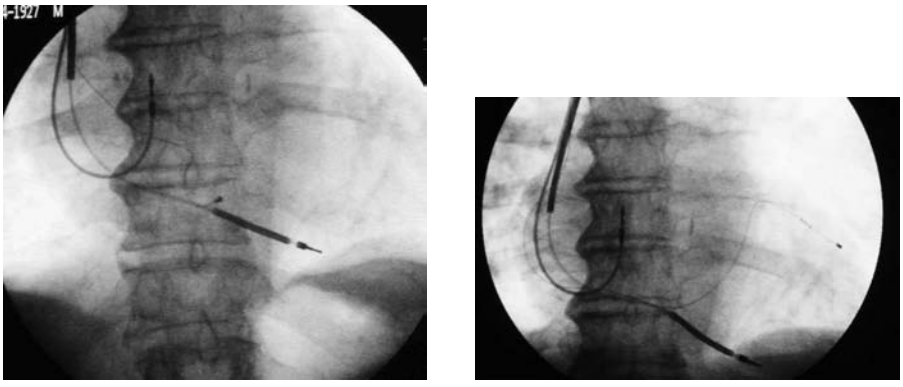

Figure 7. *Dislocation of a preshaped coronary sinus lead dislocation in the right atrium (left) and its exchange with an active coronary sinus lead (right) (Starfix, Medtronic Inc., Minneapolis, MN).*
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Unsuccessful Procedures

Procedures can be ruled unsuccessful due to an inability to cannulate the ostium of the CS main stem, failure

to cannulate the target vein (usually a posterior-lateral side branch), lead dislocation, phrenic nerve stimulation, or high thresholds. Very rarely are the problems anatomic (eg, lack of a target vein). When anatomic problems do occur, they are most frequently due to previous surgeries, especially bypasses to the circumflex artery resulting in obliteration or stenoses in posterolateral veins. In selected cases, it may be possible to dilate or even stent these bottlenecks.[18] Care must be taken to not perforate the very fragile and thin venous walls. In cases of dilated cardiomyopathy, it has to be questioned whether stenoses were caused by strictures or by the procedure itself (via dissection of the membranes).

Alternative Approaches to the Left Ventricle

From the early days of CRT, thoracic surgeons have competed with invasive cardiologists in implantation methods for LV leads. In the early years, the only possible way to place epicardial leads was via thoracotomies, as was done for the very first CRT patient by Serge Cazeau, MD.[25] Currently, however, the availability of sophisticated leads and application devices means that nearly all patients can be supplied with transvenous methods. In the rare case in which a surgeon is needed, he or she can place the leads by using minimally invasive endoscopic techniques,[26] including small incisions. Large thoracotomies should be avoided, as these techniques can cause many complications, such as chronic pain syndromes, chronic pleural effusions, pneumonia, and even acute respiratory distress syndrome. Recently, a transseptal procedure was published in a small case series.[27] However, these patients needed intense anticoagulation therapy for the long-term, making this approach unrealistic for most patients. Another way to reach the epicardium of the left ventricle is via the pericardial space. Although 1 study has examined use of an experimental device advanced via a subxiphoidal puncture,[28] more data must be collected, especially on the safety of the procedure.

Conclusion

CS lead implantation is a complex procedure with several limitations and hazards. During implantation, a resynchronization device—unlike conventional pacemakers—requires the insertion of an additional pacing lead into the coronary sinus, which is advanced into a cardiac vein to allow pacing of the left ventricle. The implantation success rate is reduced compared with conventional procedures. However, this approach can offer significant symptomatic improvement and improved prognosis when used according to guidelines. ■

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Main Points

- Selecting the right patient for cardiac resynchronization therapy (CRT) is an absolute prerequisite for a successful therapeutic response.
- Patients with normal brain natriuretic peptide levels should be carefully investigated to identify whether they have a true indication for CRT.
- CRT procedures are much longer than regular pacemaker implantations, and thus the risk of infection may be greater.
- Correct visualization techniques allow a suitable target vein to be identified in nearly all patients.
- Complications specific to CRT include ventricular arrhythmia, such as ventricular tachycardia or ventricular fibrillation; total atrioventricular block or sinus arrest without any escape rhythm; and coronary sinus dissection.

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