INNOVATIVE TECHNIQUES

A Review of Innovative Strategies for CRT Implantation: Part II — Coronary Venous Stenting

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ABSTRACT. This is part II of a review of advanced left ventricular (LV) lead implant strategies for cardiac resynchronization therapy. Discussed herein are the use of coronary venous stents for managing dissection and perforations; for advancing an LV lead into a target vein when venoplasty fails to relieve the obstruction; and for LV lead stabilization in an optimal location. Basic methodology and choice of equipment are also briefly delineated.

KEYWORDS. coronary sinus, stent, dissection, lead retention.

Introduction

An estimated 486,025 implantable cardioverter-defibrillators (ICDs) were implanted in the United States in 2009, of which 40% were cardiac resynchronization therapy defibrillator (CRT-D) devices.1 Success rates of approximately 86–96% have been reported with transvenous left ventricular (LV) leads in recent trials conducted at highly experienced centers. The morbidity and mortality of transvenous CRT lead implant remains significantly less than surgical implant.2 The following review discusses additional advanced implant techniques being used to increase success rates and reduce complications. These techniques can also be used to implant the LV lead in targeted locations within the coronary venous system, and trials are underway to explore the impact of this strategy on response to CRT.

Coronary venous stenting

Stenting of the coronary sinus and its branches is a promising new technique that is being increasingly utilized in our laboratory. As in coronary artery dissection, it can be used as a “bailout” strategy to prevent tamponade following accidental or iatrogenic dissection of the main coronary sinus or its tributaries; it can be used to retain conventional passive fixation LV leads in virtually any desired location in a coronary vein; and, finally, it is the technique of choice when obstructive lesions do not yield to venoplasty because of elastic recoil of the web-like obstructive valve.

Venous stenting for dissections and tears

Dissection of the coronary sinus can occur in several situations. The most common cause is forceful contrast injection after inflating an occlusive balloon for coronary sinus venography. It must be remembered that the pressure within the unoccluded coronary sinus is only slightly higher than the right atrial pressure under physiological conditions. When a balloon occludes the coronary sinus, the pressure then equates to the wedged coronary artery pressure, which is generally higher than the coronary venous pressure by several orders of magnitude. Forceful contrast injection can further elevate the pressure and result in rupture of the relatively thin venous wall. Figure 1 illustrates such a dissection.

Coronary sinus dissection can also occur when the guide catheter tip is lodged against the wall or against a venous valve during forceful contrast injection or due to inexpert manipulation of stiff wires or electrode catheters. Finally, dissection can occur because of inflation of an oversized balloon during venoplasty of a venous valve or stricture. Fortunately, the occurrence of tamponade is relatively rare, since the coronary veins form a low-pressure system. Also, the main coronary sinus lies within a fat pad in the posterior interventricular groove, which may further limit exsanguination into the pericardium.
Even in the absence of pericardial tamponade, occurrence of a dissection may lead to cancellation of the procedure by the cautious implanter. At the very least, it causes considerable anxiety and delay while the patient is monitored for impending tamponade.

Deployment of a venous stent is a rapid and safe way of dealing with an ominous dissection in the coronary sinus, especially when blood is documented in the pericardial space. A 0.035 guidewire is used to negotiate the dissection, and a peripheral stent is advanced to cover the area of the dissection. The stent is then deployed and a venogram obtained to confirm that the dissection has been sealed off. This venogram should be a direct injection through the guide catheter rather than a balloon-occlusive venogram. The stent should be the same size as the diameter of the coronary sinus immediately distal to the site of the dissection. Polytetrafluoroethylene (PTFE) covered stents, used for coronary artery perforations, may be superior to bare metal stents for serious perforations, especially with hemopericardium.

Dissection in a tributary of the coronary sinus is usually caused by inexpert manipulation of stiff guidewires or overenthusiastic venoplasty. In our experience, these dissections are more prone to cause hemopericardium than dissection of the main coronary sinus, possibly because the venous walls are thinner and there is no encasing fat pad. We always elect to stent such dissections, except when the patient has had prior thoracotomy or pericardial window. A bare metal coronary artery stent, sized to the dissected vessel, is used.

The following case illustrates the clinical application of some of these techniques.

Case history
A 62-year-old woman presented with New York Heart Association (NYHA) Class III heart failure symptoms, a left bundle branch block, and non-ischemic cardiomyopathy, with left ventricular ejection fraction (LVEF) of 26%. Following CRT, her symptoms improved, and LVEF was recorded at 52%. Four years later, she developed increasing heart failure and an LVEF of 30%. Device interrogation revealed an LV lead impedance >5000 ohms and loss of capture. No change in drug therapy or coronary anatomy was documented. LV lead revision and generator replacement were planned.

Initial coronary sinus angiography revealed a small anterior branch, a middle cardiac vein with a few communicating branches, and a very small proximal lateral branch. The original LV lead had been positioned in a distal lateral branch. This branch was now occluded.

To decide the optimal location for the new LV lead, epicardial activation mapping of the left ventricle was performed using a three-dimensional electroanatomic system via all available coronary veins. Using the onset of the surface QRS as reference, the coronary veins were mapped with a 0.014 BMW wire. Activation mapping revealed that both the anterior and the middle cardiac veins were activated relatively early (within

Figure 1: Stent deployment for dissection of the coronary sinus. (a) Forceful injection of contrast through the guide catheter, with the guide catheter tip lodged against the valve of Vieussens, resulted in dissection of the coronary sinus. Arrows points to a 0.035 guidewire in the lateral branch. (b) The guidewire was retained and a 5 × 35 mm peripheral balloon expandable stent positioned to cover the dissection and, incidentally, the obstructive valve (arrow). (c) A Medtronic model 4195 lead easily passed the stented coronary sinus and valve. Arrow points to contrast extravasation. (d) Final position of left ventricular lead (LV A). This patient also received another LV lead (LV B) as part of a study, and a second right ventricular lead (RV 2) as the previous RV lead was the subject of an FDA recall. Arrow points to guide catheter for second LV lead.
Selective angiography revealed no dissection, but the proximal part of the stent appeared to be relatively undersized compared with the vein. It was felt that the lead was possibly hanging up on the proximal edge of the stent. A larger balloon was then deployed to upsize and “flare” the proximal edge of the stent (Figure 4c). A subsequent angiogram revealed edge dissection, with extravasations of contrast into the pericardium (Figure 4d). Edge dissection is a known complication of coronary artery stenting and is managed by deploying an overlapping stent. This strategy was successfully adopted. A 3.0 x 10 mm stent was then deployed proximal to the previous stent and overlapping the proximal edge dissection (Figure 4e). The dissection was sealed off, and there were no sequelae. Figure 4f shows the LV lead in an optimal position.

**Coronary venous stents for lead retention**

Case reports and a single observational study describe de novo stenting for retaining LV leads in specific locations.\(^3\)\(^-\)\(^5\) In our experience, almost any LV lead can be retained in any location in a coronary vein with perfect safety and minimal expenditure of time and effort. This is particularly important when electrical or mechanical dyssynchrony mapping reveals a desired position in a relatively large caliber vessel, or thresholds are not achieved without diaphragmatic stimulation except in a specific location. Present-day passive fixation technology does not allow for reliable, unmoving LV lead retention in the proximal or middle segments of coronary veins. Even the positive-fixation mechanism of the Medtronic 4195 (Minneapolis, MN) is unreliable in veins 3.5 mm or greater in size, and this lead remains, to date, a unipolar design.

**Figure 5a** illustrates the case of a patient who had a single large lateral branch. An LV lead was positioned in several locations within this branch and its tributaries (Figure 5b,c,d,e) but either failed to capture or stimulated the diaphragm. A single location towards the
Figure 4: Coronary venoplasty and stenting. (a) Venoplasty with a 2.5 × 20 mm non-compliant balloon (arrow). (b) Deployment of 2.5 × 10 mm bare metal stent. Arrows mark proximal and distal limits of stent. (c) Proximal edge of stent flared with 3.0 × 10 mm non-compliant balloon. Arrows mark proximal and distal limits of stent. (d) Proximal edge dissection with contrast extravasation on injection (arrow). (e) Proximal 3 × 8 mm overlapping stent deployed to seal off dissection. Arrows mark limits of old stent. (f) Final left ventricular lead position.

Figure 5: Coronary venous stents for lead retention.
middle of this branch gave an excellent threshold of 0.8 volts, without diaphragmatic stimulation, but the lead position was unstable (Figure 5f). A 2.5 × 8 mm bare metal stent was then positioned to retain the lead in the only viable position (Figure 5g).

If a small (5F or lesser diameter) lead is delivered through a standard 8F guide catheter, stents up to 4 mm can be delivered through the same guide while retaining the lead. The time required for a lead retention stent in such cases is approximately 3–5 min in our laboratory. Larger stents need to be delivered via a separate guide catheter. We generally use a 6F coronary guide catheter in Amplatz 3 or multipurpose shape for this, passed through a 6F subclavian sheath. This sheath can be subsequently used to deliver the atrial lead. A 6F guide will accommodate coronary stents up to 5 mm in size without difficulty, and larger stents are rarely required. Peripheral stents 5F and larger usually require a 7F sheath.

Unlike stents used for dissection, retention stents should be smaller by 0.5–1 mm than the vein diameter at the site of deployment, as the only objective of the stent is to provide resistance to lead displacement. Also, a part of the vein lumen is already occupied by the LV lead. If the stent has been undersized to the vein, the lead may be withdrawn, completely or partially, over a stiff guidewire but never advanced. If the stent is oversized or inappropriately long, the lead may be trapped such that it cannot be withdrawn without using more invasive techniques. It is preferable to deploy the stent as close to the pacing electrode as possible for maximal stability. In practice, this is usually the tip electrode. However, the stent should not contact the cathode, as that would increase the surface area of the cathode and lead to an increase in the pacing threshold.

It must be recognized that using stents for active LV lead fixation is new and hitherto untried technology, and their use is not advocated on a routine basis until randomized trials prove their safety. There is concern, for example, about the possibility of damage to the insulation or the conductor of the lead. This seems unlikely, given that coronary artery stents are pliable objects designed to accommodate coronary artery anatomy and movement without causing damage. Balazs et al reported a case of an LV lead retained with a stent in a patient who subsequently underwent heart transplant 27 months after the procedure. The lead in the explanted heart was carefully removed and meticulously examined using optical, confocal, X-ray, and scanning electron microscopy. There was no significant damage to the surface insulation or the conductor elements. Similarly, there are reports that stenting of the superior vena cava and subclavian vein in the presence of previous pacemaker leads has not been shown to damage the leads.

Another concern is the possibility of infection involving the device and the lead. Can the lead be easily removed without resorting to open heart surgery? Geller et al have reported on three patients with stent-retained LV leads who required extraction following infection late after implant. In each case, the lead was extracted without difficulty.

We have no experience with removal of a lead held by a stent because of infection. However, we do confirm that the lead can be withdrawn over a stiff guidewire at implant if necessary. The same concern is also expressed with the use of the positive-fixation Medtronic 4195 lead, which is notoriously difficult to extract even after a couple of months in the absence of infection. In the presence of infection, leads become easier to remove, possibly due to lytic enzymes secreted by the biofilm coating the lead. We have successfully removed two chronic (>6 months) infected positive-fixation Medtronic 4195 leads with simple traction.

How does stent stabilization of the LV lead compare with the strategy of exchanging it for a positive-fixation Medtronic 4195 lead? Our experience with the latter lead has not been uniformly positive. This unipolar design is retained by “lobes” created when a thin sheath covering the lead is crumpled close to the distal tip of the lead. Unfortunately, the lobes are not large enough to stabilize the lead in a large vein. Deployment of the lobes can also cause the lead to “accordion”, and the tip can shift its location. The cost of changing the lead is also significantly higher than deploying a stent. Using stent stabilization, the lead may be positioned anywhere in the coronary venous system with minimum expenditure of time. This strategy is also much quicker than trying to position the lead in another side branch or in a second-order branch.

Coronary venous stenting can be very safe and effective if performed by appropriately trained physicians. Familiarity with interventional equipment and techniques is necessary for success. The following points should be kept in mind while employing these techniques:

- Only bare metal stents of appropriate length and caliber for the application should be deployed. The only possible exception is deployment of a long stent in a low-flow main coronary sinus, where occlusion of the stent by thrombus may have serious consequences. In such cases, a drug-eluting stent may be chosen, but appropriate antiplatelet therapy will then be required. Our experience in this regard is limited, and there are no published data to support or refute this viewpoint.
- PTFE covered stents may be preferable to bare metal stents for major dissections with hemopericardium. They are superior to bare metal stents for coronary artery perforations but cost more.
- Occlusion of even large side branches is clinically inconsequential because of extensive collateral circulation. The branches where LV leads have been placed chronically are almost invariably occluded. Hence, there is no indication for a drug-eluting stent in a side branch coronary vein. Antiplatelet agents are not required for bare metal stents in side branches for the same reason.
- Coronary veins are distensible vessels, and unless a selective venogram is obtained with a forceful injection of contrast, the tendency is to undersize the stent. For dilating lesions or sealing dissections, the stent should be slightly larger than the apparent diameter of the vein, especially if a non-selective venogram was used to determine vein size.
- For lead retention, the shortest available stent should be deployed. It should be approximately 0.5 mm smaller than the apparent vein diameter, since the vein will
accommodate the stent as well as the lead. This successfully retains the lead in position while allowing withdrawal of the lead over a stiff guidewire if necessary.

- It is important to obtain an angiogram after stent deployment to document good flow and absence of dissection.
- If the lead hangs up on the proximal edge of the stent and there is no edge dissection, advancing the lead with a stylet rather than over a guidewire may prove successful. If this maneuver fails, the proximal edge of the stent can be slightly flared with a larger balloon.

References