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Techniques of Implantation of a Biventricular Pacing System

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ABSTRACT

Cardiac resynchronization therapy (CRT) was conceived in the mid-1990s. It offered not only atrioventricular (AV) synchronization as had previously been used in dual chamber pacing but also synchronization of the two ventricles. By pacing the region of the left ventricle (LV) with the most delayed activation, it was possible both to improve interventricular synchrony and the synchrony of the LV itself. A brief review of the current techniques achieving this purpose is attempted.

INTRODUCTION

In early '90s, the purpose of attempting to pace the left ventricle through the coronary sinus (CS), was not for biventricular pacing, but for single chamber (VVIR) pacing in special circumstances, like the presence of a mechanical prosthesis at the tricuspid valve. Due to the absence of the necessary tools for CS catheterization (specially designed sheaths and leads), a pacing lead was designed to achieve cannulation of the CS (Medtronic, Minneapolis, MN, USA; Model 2188 & 2187). Those attempts showed that LV pacing was feasible through the CS, and the idea of biventricular pacing was generated.¹ Such a case is shown in figure 1.

At the outset of cardiac resynchronization therapy (CRT), many pacing problems had already been overcome. For example, rate modulation in the absence of normal sinus node behaviour, mode switching from DDD to VVI or DDI for atrial tachyarrhythmias, and algorithms to avoid pacemaker-mediated tachycardia were all standard and well understood in the dual-chamber device of the mid-1990s. Some inspired work anticipated the introduction of CRT. Most notable work was that of the Rennes group in attempting to resynchronize the atria in interatrial conduction block² and in Lausanne, where desynchronization of the LV by right ventricular (RV) apical pacing was employed to reduce LV outflow obstruction and treat hypertrophic obstructive cardiomyopathy.³

Cannulating the CS to place an LV lead is widely recognized as the most challenging aspect of implanting biventricular pacing devices for achieving CRT in patients with heart failure (HF) and ventricular dyssynchrony⁴. Typically, the LV lead is introduced transvenously into the CS in order to reach the left lateral wall of the ventricle, which is the target area for LV stimulation. This approach is successful in the vast majority of patients; however, variability in patient anatomy, particularly in those with severe HF and significant heart remodeling, can make it difficult to access the CS and/or the

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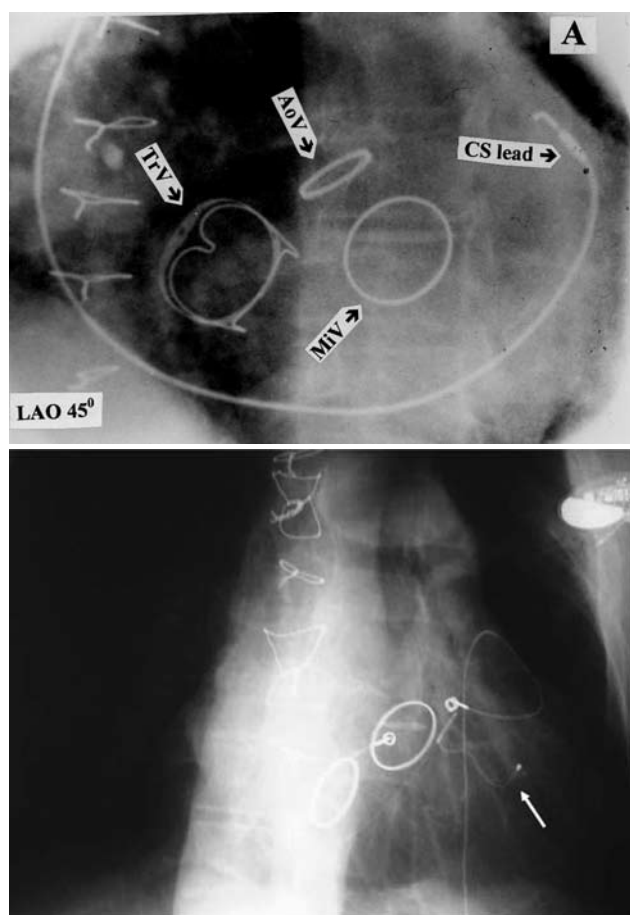


FIGURE 1. A case of an attempt for left ventricle lateral wall pacing, is shown. In early '90s, the purpose of this attempt was not the biventricular pacing, but VVIR pacing in a patient with 3 prosthetic valves. Due to the absence of the tools necessary for coronary sinus (CS) catheterization (special designed sheaths and leads that exist today), a pacing lead was designed to achieve it (Medtronic, Minneapolis, MN, USA; Model 2188 or 2187). Those attempts showed that the LV pacing is possible through the CS, and the idea of biventricular pacing was generated (Kappos KG, et al: 1993, unpublished data). **B:** Transvenous permanent pacing lead placement in the presence of prosthetic metallic tricuspid and mitral valves (Manolis AS, Kappos KG et al. Heart Rhythm 2005)

venous tributaries and can sometimes prevent the lead from being placed appropriately.

DESCRIPTION OF THE METHOD

CRT as it exists today is centered around adding an LV pacing lead to a standard pacemaker or defibrillator system to pro-

vide pacing of both ventricles either simultaneously or with a programmable offset in order to resynchronize the activation of both ventricles. Typically, the LV lead is passed through the coronary vein in the right atrium (RA) to the venous tributaries in order to access the left lateral wall of the ventricle. This is performed under conscious sedation without opening the chest. The advantages of the transvenous approach include: 1) reduction of the risk (surgery and anesthesia), 2) reduction of the implant time and complexity, 3) reduction of the hospital stay, and 4) reduction of patient's morbidity. Some caveats regarding biventricular pacing can be emphasized: it is different from conventional pacing and it entails a prolonged procedure; right vs. left sided approach differs; there is need for optimal fluoroscopy (duration, angulations, image store) since angioplasty guide wires are employed, and it is a team approach with people experienced in electrophysiology (EPS) and angioplasty (PTCA) involved in a tedious procedure.

TRANSVENOUS APPROACH

Firstly, standard pacing leads are implanted in the right atrium (RA) and the right ventricle (RV), while a specially designed LV lead is placed in a left cardiac vein via the coronary sinus⁵. A six step implant process has been proposed: 1) Cannulation of CS, 2) Performing venograms, 3) Selecting leads, 4) Placing leads, 5) Removing implant tools, and finally 6) Measuring final electrical parameters and device programming.

The need for backup pacing should be considered. If needed, an RV lead should be implanted first, that can be used to provide backup pacing, while it may be more difficult to cannulate the CS with the lead implanted. If there is no need for backup pacing or additional method is used to provide backup pacing (e.g. temporary RV apex pacing), the LV lead should be implanted first, because it may be easier to cannulate the CS. Regardless which ventricular lead is implanted first, the RA lead should be implanted last, in order to avoid dislodgements. In our department, we proceed with the following strategy: first we obtain venous access via the cephalic or subclavian vein or both, we use a long guide wire in the vein(s), and employ standard or active fixation RV lead or defibrillator lead which is implanted first at a traditional (RV apex) or an alternate site (mainly the intraventricular septum). The RA lead is advanced in the inferior vena cava and is implanted last either at the RA appendage or at an alternate site (intra-atrial septum). Through the long guide wire, which is in place, the specially designed and curved long sheath (catheter) is advanced in the right atrium, preparing the CS cannulation.

CS CANNULATION

All necessary tools for CS cannulation included in the manufacturer's package: Guide catheters (straight or pre-shaped with different degrees of the curves, or straight cath-

eters with the ability of cyrtosis by external manipulation), dilators, hemostatic valve(s), long guide wires, slitters (depending upon whether the catheter is peel-away or not), standard Josephson type diagnostic electrophysiology catheter or steer-

able quatripolar ones, and soft PCI guide wire with a torque. All delivery system components should be prepared before the procedure starts by flushing all lumens with heparinized saline. Flushing and testing of the balloon catheter many times, is mandatory. Then the hemostatic valve is attached to the guide catheter hub. The guide catheter assembly is passed over long introducer guide wire through introducer sheath to the atrium. The guide wire should always be used when advancing catheters into the heart. The hemostatic valve is secured tight to avoid excessive blood loss. Different types of hemostatic valves are available in the market depending on the manufacturer. Knowledge about how the hemostatic valve is working is mandatory in order to avoid hemorrhage or air embolism. Extreme care should be used when passing the guide catheter through vessels.

Due to the relative stiffness of the catheter, damage to the walls of the vessels may include dissections or perforations (Fig. 2). The guide catheter is advanced till the mid or low RA, guided by fluoroscopy, the dilator and the guide wire are withdrawn. Some operators do not withdraw the long guide wire and try to cannulate the CS with the guide wire. According to our experience it can be achieved only by chance, if the CS-os is like "a funnel". The best approach is to insert a steerable electrophysiology diagnostic mapping catheter in order to locate the coronary sinus ostium (Fig. 3). As the catheter is approaching the ostium, a characteristic increase in amplitude of the atrial component of the electrogram as compared to the ventricular signal is noted. When such a typical signal is obtained, the catheter is carefully advanced into the CS under fluoroscopic guidance in the LAO 30-45° view. The sheath is advanced over the EP catheter and the EP

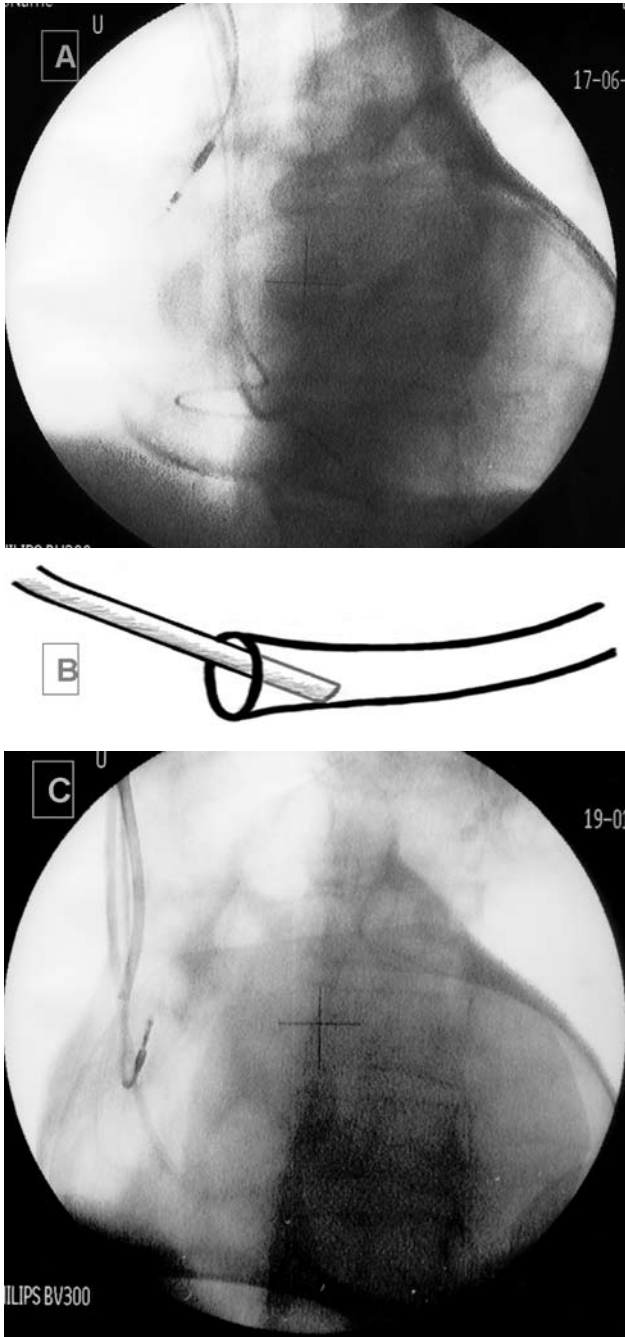


FIGURE 2. Due to the relative stiffness of the catheter, damage to the walls of the vessels may include dissections or perforations (B). Such a case is shown here. Contrast infusion led to pericardial cavity delineation (A & C), followed by tamponade.

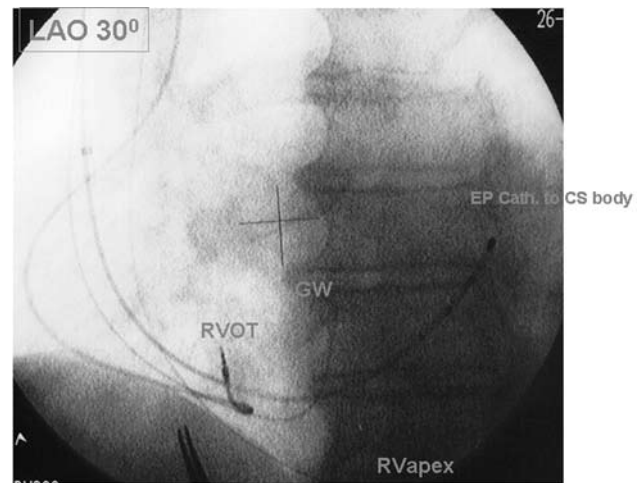


FIGURE 3. The best approach is to insert a steerable electrophysiology diagnostic mapping catheter in order to locate the coronary sinus ostium and advance the catheter to CS body.

TECHNIQUES OF IMPLANTATION OF A BIVENTRICULAR PACING SYSTEM

catheter is withdrawn. A small amount of contrast is infused in order to confirm the location of the sheath in the coronary sinus (and not in RV outflow tract) (Fig. 4A). This approach is particularly helpful in severely dilated hearts with distorted geometry and significant displacement of CS ostium upwards and leftwards. Remodelling of the heart results in a series of anatomical changes that pose significant problems in the cannulation of the CS. The Eustachian ridge, which comprises the bottom part of the crista terminalis, lies just posterior to

the coronary sinus ostium and is the most significant obstacle (Fig. 5). The Eustachian ridge is more resistant to dilatation than the adjacent tissue and consequently becomes more prominent. Therefore the guiding catheter will always find this obstacle and lie against it. Moreover, significant tricuspid regurgitation not only poses an additional stretch to the right atrium but also makes manipulation of catheters and wires in the right side of the heart challenging. Patients with prior cardiac surgery usually have distorted venous anatomy and

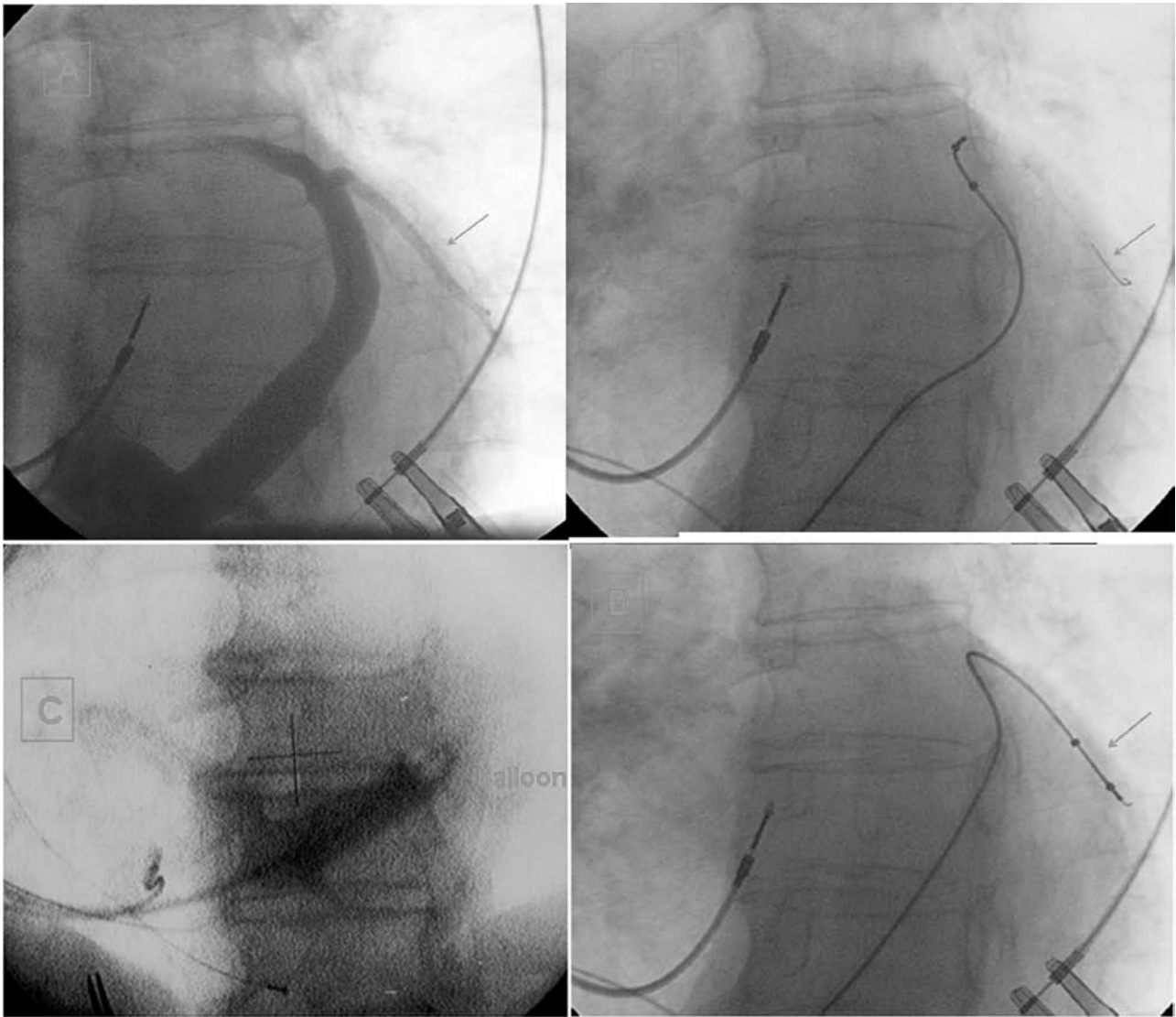


FIGURE 4. A: contrast infusion confirms the location of the sheath in the CS body, and simultaneously outlines a target left lateral vein without the use of balloon catheter (see further). **B:** a guiding PCI wire is advanced through the pacing lead in the target vein. Using the technique “over-the-wire”, the bi-polar pacing electrode is advanced in the target vein (D). **C:** Inject contrast in order to verify location, thereafter inflate the balloon. Do not use too much pressure. See to that the catheter tip is not blocked against the vein wall. Avoid inflating the balloon where it possibly could damage the vein. **D:** RV bi-polar active fixation lead in mid-septum (alternate site pacing), is also seen. Make sure that there is not phrenic nerve stimulation by pacing the LV in high output pacing threshold and during inspiration and exhalation.

may present with significant difficulties as well. In order to overcome these problems a series of products such as different sizes and shapes of guidewires and special sheaths can allow for adjustable curves and navigation around the obstacles using the “catheter- within- a-catheter approach”^{6,7}.

The delivery sheath is then manipulated over the EP catheter which is exchanged for a balloon catheter in order to perform a venogram⁸ (Fig. 4A)⁸. The balloon catheter is inflated (Fig. 4C) after injecting small amounts of contrast in order to verify the location and make sure that the catheter tip is not blocked against the vein wall. As an alternative a guide wire may be used for identification of position. A venogram is recorded for future reference regarding lead placement. AP, LAO 45° and RAO 30° are the standard views recorded in order to understand which veins are present, their location along the left ventricular wall, their size, tortuosity and angulation. The LV lead is then advanced usually using an

angioplasty guidewire in a suitable branch preferably in a lateral or posterior-lateral position on the LV (Fig. 4B, 4D). A guiding catheter such as a 5F Judkins right coronary type may be advanced through the delivery sheath for extra support and ease of manipulation of the wire. The lead tip is advanced past the desired cardiac vein and the stylet or the wire is partially withdrawn. The lead is rotated in order for the tip to align with the desired vein and then it is slowly pulled back until the tip slips into the desired vein. Once the lead is advanced in the desired position, lead measurements are performed in order to specify pacing and sensing threshold and to detect any phrenic nerve stimulation (2-3% of cases). Following successful LV lead implantation, the right ventricular and right atrial leads are implanted⁹.

There are a number of anatomic challenges that can affect our ability to insert a guidewire and a guide catheter so that we can reliably work within the CS to place an LV lead in the desired coronary vein. Vieussen’s venous valve between the coronary sinus and the great cardiac vein may be responsible for up to 80% of unsuccessful attempts to advance the guide catheter (Fig. 6). Congenitally or acquired big coronary sinus and lack of support, acute angulation and tortuosity of vessels, systolic compression, restrictions or stenoses of the coronary

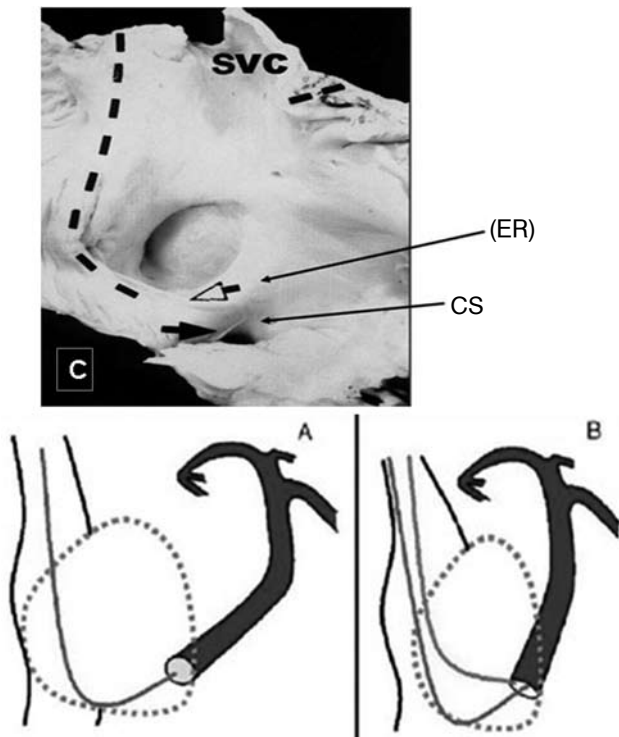


FIGURE 5. C: Right atrial anatomy: superior vena cava (SVC), Eustachian ridge (ER), and coronary sinus (CS). Coronary sinus in the normal heart (A) vs failing heart (B). Remodeling occurs in all chambers of the heart as a result of ventricular failure. As the left ventricle enlarges, the heart begins to rotate and the mitral annulus unfolds and becomes stretched and distorted, which affects the angles within the CS. In addition, many HF patients develop tricuspid regurgitation, which puts a greater load on the RA, and elevated central venous pressure. All of these things conspire to stretch the RA, and because of the RA’s interesting anatomy, there’s a differential effect on the tissues.

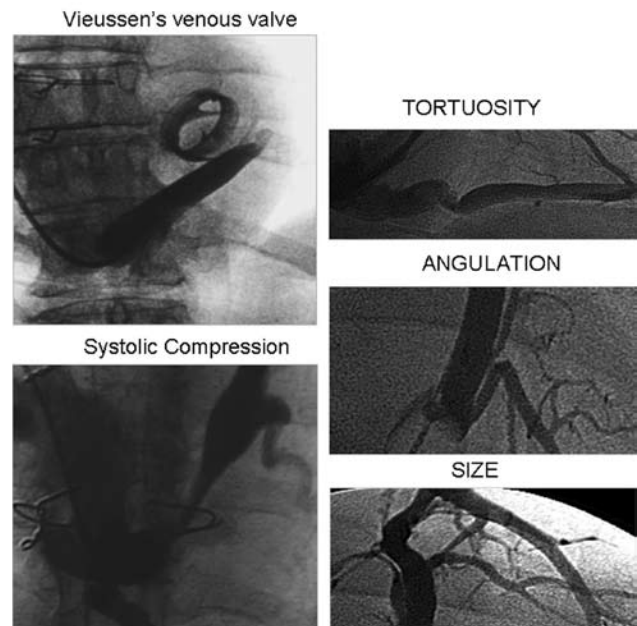


FIGURE 6. The high variability of the CS venous anatomy. The size, angulation, tortuosity, systolic compression and vieussen’s venous valve are the most common seen anatomic variations. The vieussens valve between CS body and great cardiac vein, is responsible for up to 80% of difficults to advance in great cardiac vein. The knowlege of CS anatomy and variations, identifies the LV lead placement strategy.

sinus or the great cardiac vein, kinking of the wires or leads due to elastic recoil of a tightly angulated coronary ostium pose major difficulties that preclude successful implantation¹⁰ (Fig. 6).

Even if the LV pacing lead is successfully advanced in the desired vessel, it may not capture adequately or it may stimulate the diaphragm. Dislodgement of pacing leads may occur especially in angulated, tortuous vessels and scars due to previous myocardial infarction may result in unacceptably high pacing thresholds. Even fat layers around the veins may cause an increased pacing threshold. Lower thresholds will likely be obtained in more distal or mid to apical sections of the coronary veins due to the relatively smaller caliber where pacing leads fit better. In humans the veins taper from base to apex and in experimental data, the threshold averages were about 6 volts at the base and in some patients actually exceeded 10 volts. For this reason a mid to apical placement is recommended in an attempt to achieve acceptable pacing threshold.

As for the phrenic nerve stimulation, it is a major cause of failure in the implantation of a biventricular pacing device (Fig. 7). Stimulation may be variable depending on the posture or respiration and it is more common with the implantation of LV lead in the posterior or posterolateral branches. In order to overcome this problem many approaches have been described. Change in the orientation of the tip of the lead, change in the current pathway, repositioning more medially or proximally in the same branch, or repositioning of the lead in another branch are some of the available options after a thin safety margin between pacing and stimulation threshold has

been established. On top of these technical problems, major complications may occur at a rate between 2-3% and include coronary sinus dissection (Fig. 2), or cardiac perforation, both of which can result in tamponade or air embolization¹¹.

CONCLUSION

CRT is different from conventional pacing and ends up to be a prolonged procedure. Cannulating the coronary CS for LV pacing lead placement is one of the most challenging aspects for device implantation and it can increase the complexity, duration, and risk of the procedure, even for experienced physicians. There is a learning curve to this procedure. Implanters who have a lot of operator experience have failure rates less than 5%, highly dependent upon available tools, as well as patient's anatomy. The success rate of 85%-92%, that is referred to the initial trials, occurred years ago, before the availability of the "over-the-wire – OTW" delivery systems. Technical advances in delivery systems, availability of multiple LV lead designs, and increased implantation experience of individual operators have led to significant decreases in procedural and fluoroscopic times. Furthermore, it is recommended that total procedure time be kept under 4 hours to minimize complications.

If a CRT defibrillator is placed and the procedure duration is long or the patient becomes unstable, consideration should be given to deferring defibrillation threshold testing to a later date. Intracardiac echocardiography (ICE) has emerged as a useful tool to guide precise catheter placement



FIGURE 7. Middle cardiac vein pacing avoids phrenic nerve stimulation, offers optimal resynchronization and obviates surgery for epicardial lead placement. (Manolis AS, Kappos KG, et al. Hospital Chronicles 2007;2:44-45).

during electrophysiologic procedures. ICE facilitates direct visualization of the CS ostium and overcomes some of the limitations associated with standard fluoroscopy, such that ICE can detect the presence of valves and fenestrations that may obstruct the CS opening. Magnetic guidance navigation system, originally designed to guide ablation catheters and angioplasty guide wires remotely, the *Niobe* magnetic navigation system (Stereotaxis, St. Louis, Missouri) has also been used to guide LV lead implantation for CRT. The system uses 2 large magnets arranged externally around the table that interact to form a magnetic field within the patient. A guide wire with a tiny magnet at the distal tip aligns itself with the direction of the magnetic field, allowing controlled and precise movement.

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