

Reducing Coronary Sinus Access Times for Left Ventricular Lead placement

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Time is what we all lack and need more of.

The EP Lab is well known for its long procedure times and consequently, long work-days. The longer the procedures, the more costs are incurred to operate the Lab. The search for opportunities to reduce case times and the supplies used during procedures is critical to make a profit and maintain case schedules. This is especially true for Bi-Ventricular (Bi-V) device implant procedures, where case times can vary widely.

During Bi-V implant cases there is an opportunity for time savings during placement of the left ventricular lead into the Coronary Sinus (CS), specifically the initial insertion of a guide sheath into the CS. Accessing the CS can be a challenging and time consuming process. Valves, ridges, and unexpected anatomical differences (due to natural or surgical causes) can increase the time required to access the CS.

These anatomical challenges can make insertion of a guide sheath into the CS a daunting task to tackle with only a wire inside a sheath. In our experience, this method for sheath placement is not efficient. A wire does not provide the proper control necessary to access the CS in a short time. A wire has limited “push-ability” and no steering ability, and can therefore make this part of the Bi-V implant procedure time consuming and exhausting. Frequently, the use of multiple wires and sheaths is required making initial access to the CS an expensive and inefficient exercise.

The Bard® CS Assist Specialty Catheter

The CS Assist catheter was developed to address the need to find advanced time saving technology to access the coronary sinus from the subclavian vein for Left Ventricular (LV) pacing (See Image 1). It is a 6 French deflectable tip catheter with a short 65cm usable length, and has 2 electrodes with 5mm spacing.

It is made of a flexible material that provides the push-ability, outstanding steerability, and support needed for these procedures, as well as great ergonomic control. When used inside a CS sheath the CS Assist catheter opens the opportunity for significant time savings.

The handle supplies the proper ergonomic characteristics required to comfortably hold the catheter. It is also suited for sterile lead glove users. The push-pull knob is situated and sized to allow manipulation of the distal curve with a minimal amount of time and concentration, allowing the user to focus on electrograms and patient anatomy. The curve is extremely sensitive to micro-

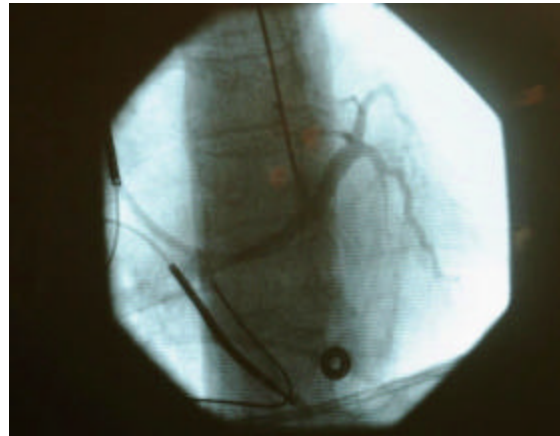


Image 1 – Coronary Sinus Anatomy

manipulations which are very useful when trying to surmount a ridge at the Coronary Sinus Ostium (CS os). The shaft of the catheter offers the proper push-ability to aide in “deep-throating” a CS sheath through a valve that is obstructing pass through of the lead. This support has been a great aide to us as we have come across this problem multiple times. The CS Assist has shown the ability to do this quickly, and without damage to the CS.

Having mapping capabilities with the bipolar electrode configuration of the catheter is a definite advantage – the ability to receive an intracardiac signal in distorted or difficult cardiac anatomy is extremely beneficial. This has helped us locate the CS os during several procedures.

Time Savings Analysis

A time savings analysis was conducted during 10 Bi-V device implant cases to assess the benefits of using the CS Assist Specialty Catheter versus the use of a traditional guide wire for placement of a sheath into the CS. Time was monitored starting from when the sheath entered the Right Atrium (RA) from the left subclavian vein to when the sheath was successfully placed in a stable position within the CS.

In 4 cases, the use of a guide wire was chosen as the initial technique for accessing the CS and successful sheath insertion was completed in less than 15 minutes. These “typical CS access” cases had an average placement time of 8 minutes (range of 4-12 min).

In 4 other cases, the use of a guide wire was chosen as the initial technique for accessing the CS, but successful sheath insertion was not achieved after a period of time averaging 28 minutes (range of 18-40 min). It was determined by the physician that the insertion would be unachievable within a reasonable amount of time using the traditional guide wire placement approach due to difficult anatomy. The guide wire

was retracted and replaced with a CS Assist Specialty Catheter. Successful insertion of the sheath was completed in each case with an average time of 12 minutes (range of 8-12 min). This represented over 50% reduction in time spent to place the sheath vs. the guide wire in these “difficult CS access” cases.

In 2 cases, it was determined by the physician that using a guide wire to place the sheath into the CS had a low chance of success due to concerns about difficult anatomy identified during the initial patient assessment. In these cases, the CS Assist Specialty Catheter was chosen as the initial technique of choice. Successful insertion of the sheath into the CS was completed in each case with an average time of 18 minutes (range of 18-22 min). Even though an attempt was not made to place the sheath into the CS with a guide wire, it was felt that it would have been extremely difficult to achieve successful insertion in a reasonable amount of time.

Placement Technique

A long wire and CS Sheath is inserted via the subclavian vein into the RA (in a 20-degree LAO view). An angled CS sheath is ideal for this maneuver. The CS Assist is compatible with sheaths under 50cm in length. Remove wire and dilator from the sheath, and flush the sheath with heparanized saline. Then rotate the distal end of the sheath towards the tricuspid valve in a counter-clockwise motion until pointing towards the septum

At this point insert the CS Assist catheter into the sheath. Connect the 6ft. tail to the catheter and the pins to the pacing block, and display the corresponding intracardiac signals on the screen. Actuate the deflectable curve to a 10 to 20 degree curl and advance slowly to the septum using slow deliberate sweeping motion until an acceptable CS waveform is located (A-V interval).

Once the CS has been located, advance and cannulate the CS Assist slowly until the catheter is stable within the CS. Push the CS sheath into the CS vessel until it is also stable and then remove the catheter. At this point in the procedure it is normal protocol to take a fluoroscopic angiogram of the CS anatomy to prepare to introduce the wire and lead.

Case Study

A 65 year old female patient presented with heart conditions indicated for cardiac resynchronization therapy using a Bi-V implantable device. During initial attempts to insert a sheath into the CS using a guide wire, it was identified that her CS os has an acute angle CS take-off. After 18 minutes, we removed the wire and introduced the CS Assist Specialty Catheter. We located the CS using intracardiac signals within 3 minutes. Once the CS OS was located we tried to access the CS quickly, but a ridge in the OS blocked full access. We advanced the sheath to the OS and removed the catheter

In this application, we found that the extreme angle of the CS take-off caused the CS sheath to bend at its curve and

thereby not providing the support needed for the wire (See Image 2).

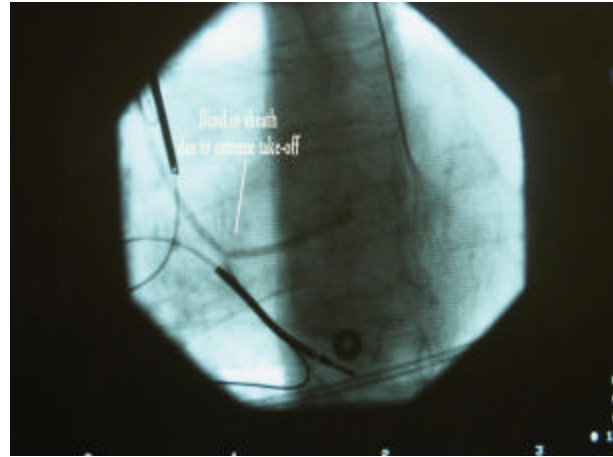


Image 2 – No support to CS sheath causing the sheath to bend and split

The CS Assist Specialty Catheter was then placed back into the sheath, shaping the curve and taking out the excessive bend. With the ability to produce micro-movements at the distal tip of the catheter we quickly navigated over the ridge and pushed the catheter into position.

We then advanced the sheath (using the available catheter support) over the ridge and placed it firmly into the CS. At this point, the LV lead could then be advanced into the CS with the shape of the sheath stabilized (See Image 3).



Image 3 – Shows proper support being given to the CS sheath

Conclusion

Trying to use a guide wire would have added a large amount of time and effort to the procedure. Achieving CS access over the ridge would have been impossible to navigate and produce a stable platform for lead advancement. Locating the CS, in this case, was very difficult with a wire that did not provide enough support for the sheath. Alternatively, by using intracardiac signals and a short catheter with a deflectable tip, locating and accessing the CS became a quick and successful procedure.

Disclosure

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