Novel Approach for Biventricular Pacing: Utilizing Temporary Coronary Sinus Catheter Guidance via a Femoral Vein Approach

THOMAS E. WATTS, MD, DALIP SINGH, MD, ASIF SEWANI, MD, HEATHER ECKLUND, RT(R) and HAKAN PAYDAK, MD

Department of Internal Medicine, University of Arkansas for Medical Sciences, Little Rock, AR
Department of Cardiology, Medical College of Wisconsin Affiliated Hospitals, Milwaukee, WI
Division of Cardiology, University of Arkansas for Medical Sciences, Little Rock, AR

ABSTRACT. Background: Placement of a left ventricular (LV) lead can be difficult due to anatomical variations and structural heart disease, as well as valves at the coronary sinus (CS) ostium. An alternative technique is cannulating the CS temporarily via the femoral vein (FV) prior to placing the LV lead. Aim: To document whether there were differences in fluoroscopy times (FT) and procedure times (PT) utilizing an FV approach for CS cannulation in LV lead placement. Methods: We performed a retrospective chart review of 166 patients at the Zablocki VA Hospital who had initial LV lead placement per standard indications defined by current guidelines. We compared patients undergoing an FV approach versus those undergoing a standard approach. Exclusion criteria: upgrades, no data recorded, generator replacement. We included 135 patients, 60 in the FV group (including 1 patient who crossed over from the non-FV group) and 75 in the non-FV group. Two equally experienced operators were identified; one exclusively used the FV approach and the other used the standard approach plus the FV approach for right-sided implants only (n=4). Results: FTs for the FV group averaged 44.4 ± 28.8 minutes (min) and FTs for the non-FV group averaged 39.7 ± 32.76 min (p=0.1945). There was no statistically significant difference between groups. PTs for the FV group averaged 3.66 ± 1.1 hours (h) (including the average 28 min required to cannulate the CS via the FV, chest preparation and operator scrub-out and scrub-in times). PT for the non-FV group was 2.88 ± 1.7 h (p=<0.001). The median difference is 1.1 h longer in the FV group with a 95% median CI of (0.6, 1.5) h. There were no procedural complications including where the FV approach was utilized. Conclusions: There is no significant difference in FT between the two groups. However, there is a significant difference in the PT between the two groups, favoring a shorter PT in the non-FV group. Operator differences may have played a role in this. Furthermore, CS cannulation by the FV approach delayed the remainder of the procedure by 28 min on average, thus contributing to the longer PT in the FV group. Nevertheless, this remains a unique alternative technique that should be considered in any patient with difficult or unusual anatomy.

KEYWORDS. biventricular ICD, cardiac resynchronization therapy, temporary coronary sinus catheter.

Introduction

In patients with a left ventricular ejection fraction of less than or equal to 35%, New York Heart Association class II to IV symptoms, and QRS duration of 150 ms or greater with left bundle branch block, cardiac resynchronization...
therapy (CRT) has been demonstrated to improve quality of life, functional capacity, and survival.\textsuperscript{1} CRT implantation is technically difficult and presents a unique set of challenges to even the most experienced operator.\textsuperscript{2} Several trials report failure rates of up to 10% due to unsuccessful cannulation of the coronary sinus (CS) or unsuccessful placement of the left ventricular (LV) lead into a targeted branch.\textsuperscript{3} Initial cannulation of the CS for LV lead placement can often be quite challenging and can lead to increased fluoroscopy times (FTs) and increased procedure times (PTs). Multiple anatomical barriers to successful CS cannulation may exist, including but not limited to: prominent Eustachian ridge, Thebesian valves, and the valve of Vieussens.\textsuperscript{4,5} In addition, the ostium of the CS may be higher or lower than usual in patients with structural heart disease, congenital heart disease, or prior cardiac surgery, leading to difficulty in cannulating the CS. The standard approach to CS cannulation during CRT implantation is a superior one via the cephalic, axillary, or subclavian vein.\textsuperscript{6}

In this study we describe an alternative technique of cannulating the CS with an electrophysiology catheter via the femoral vein (FV). Subsequent cannulation of the CS with the delivery sheath from the standard superior approach is carried out using the FV catheter as a guide. Upon satisfactory delivery of the LV lead to the desired target vein, the catheter introduced via the femoral vein is withdrawn with the LV lead delivery sheath still in place. The remainder of the CRT implantation is completed in the usual fashion.

**Methods**

**Study methods**

In order to determine the success of this novel approach, we conducted a retrospective review of all patients who had CRT devices implanted at the Zablocki VA Medical Center in Milwaukee, WI, from September 2002 to December 2007. Our hypothesis was that initial cannulation of the CS from the femoral vein correlated with a shorter PT and FT, as compared to the traditional approach. No randomization or blinding criteria for diagnostic tests are applicable in this study. This was a retrospective chart review of patients at our center who have undergone this procedure. No cost-effectiveness or cost–benefit analysis is applicable.

We performed a retrospective chart review of 166 consecutive patients who had initial CRT per standard indications as defined by guidelines at the time this study was performed. We compared patients undergoing an FV catheter approach (FV group) versus those undergoing a standard approach (non-FV group). Exclusion criteria were: upgrades (20), no data recorded (9), generator replacement (2). Our list included 135 patients, 60 in the FV group (including one patient who crossed over from the non-FV group) and 75 in the non-FV group. Two equally experienced operators were identified: one exclusively used the FV approach and the other used the standard approach plus the FV approach for right-sided implants only (n = 4).

After Institutional Review Board (IRB) approval was obtained, a data template was created and data were collected from the electronic medical record and entered into the database. The data included age, sex, right atrial dimension, left ventricular ejection fraction, ischemic versus non-ischemic cardiomyopathy, medications, operator, significant comorbidities such as diabetes and tobacco use, and site of implantation (right or left). A comparison of baseline characteristics was performed. A statistical method using unpaired t-test (continuous data and dichotomous data) was used. Primary outcomes (FT, PT) were analyzed. Patients were divided into two groups: those undergoing LV lead placement using an FV catheter as a guide for CS cannulation (FV group) and those undergoing a standard approach (non-FV group).

**Procedural methods**

All patients with an indication for CRT (with or without a defibrillator) were given intravenous antibiotics at least 30 minutes (min) prior to the procedure. Conscious sedation was administered and 1% lidocaine was injected at the pre-pectoral site of device implantation. In patients in whom the FV approach for CS cannulation was adopted (FV group), the skin overlying the right common femoral vein was infiltrated with 1% lidocaine prior to venipuncture and an 8-Fr locking short side-port sheath was introduced via a modified Seldinger technique. This sheath was secured with a silk suture. A dynamic decapolar electrophysiology catheter (Bard

<table>
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<th>N</th>
<th>Mean</th>
<th>Standard deviation</th>
<th>Minimum</th>
<th>Median</th>
<th>Maximum</th>
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<td>FV group</td>
<td>60</td>
<td>3.661 h</td>
<td>1.080 h</td>
<td>2 h</td>
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<td>Non-FV group</td>
<td>75</td>
<td>2.884 h</td>
<td>1.701 h</td>
<td>1 h</td>
<td>2.4 h</td>
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Table 2: Procedure time between groups
Figure 1: CS ostium low takeoff.
Figure 2: CS ostium high takeoff.
Figure 3: Subselective cannulation of the posterolateral branch.
Figure 4: Shepherd’s crook CS anatomy.
Electrophysiology, Murray Hill, NJ) was then inserted into the femoral vein introducer sheath and maneuvered to the right atrium under fluoroscopic guidance. The CS was then cannulated under fluoroscopy using the electrophysiologic and anatomic parameters previously described. After placing the CS catheter, cineangio-
grams of the CS catheter were taken in anteroposterior (AP), left anterior oblique (LAO), and right anterior oblique (RAO) projections. The operator then rescrubbed for placement of the biventricular system.

In patients in whom the standard approach for CS cannulation was used (non-FV group), a long sheath was passed over an electrophysiology catheter via the axillary, cephalic, or subclavian vein into the coronary sinus. A balloon tipped catheter was then passed into the coronary sinus and a test injection carried out to demonstrate an intraluminal position. Balloon occlusion venography of the epicardial LV venous system was then performed and the balloon catheter was then withdrawn.

In the FV group, the CS catheter from the FV was removed prior to taking out the coronary sinus sheath after LV lead placement. The coronary sinus sheath was then removed while monitoring the LV lead position fluoroscopically. The lead was secured to the pectoral fascia with three non-absorbable sutures. Finally, both operators performed cineangiograms of the LV lead position in the AP, LAO, and RAO projections at the end of the procedure.

**Statistical analysis**

The Mann–Whitney test and confidence interval was used for FV versus non-FV group comparisons and estimates of the median difference. A significance level of 0.05 was used. This analysis was performed using MINITAB version 12.0 (MINITAB Inc, State College, PA, USA).

**Results**

Comparisons of patient demographics in the FV and non-FV groups were not statistically different. Results were divided into two categories: FT and PT. FT for the FV group averaged 44.4 ± 28.8 min and for the non-FV group was 39.7 ± 32.76 min (p=0.1945) (Table 1).

PT for the FV group averaged 3.66 ± 1.1 hours (h) (including the average 28 min required to cannulate the CS, chest preparation and operator scrub-out and in times). PT for the non-FV group was 2.88 ± 1.7 h (p=<0.001). The median difference is 1.1 h longer in the FV group with a 95% median CI of (0.6, 1.5) h (Table 2).

There were no procedural complications in either group. Based on these results, it is evident that FT and PT are not shorter in the FV group. Therefore, there does not seem to be an advantage with respect to FT or PT using the FV approach for CS cannulation.

**Discussion**

The current standard approach to LV lead placement during CRT implantation is via the axillary, cephalic, or subclavian vein for CS cannulation. Although there is no improvement in FT or PT, the FV approach is an important technique to master for cases of abnormal or difficult CS anatomy. A review of the literature reveals several studies reporting the incidence of obstructing Thebesian valves. Silver and Rowley reported a 12% incidence of Thebesian valves leading to >75% obstruction of the CS ostium. In addition, Hill et al found 27% of subjects studied had Thebesian valves leading to >50% obstruction of the CS ostium. Karaca et al found that 8% of examined subjects had Thebesian valves that would result in low probability for CS cannulation. Anh et al reported the characteristics of CS anatomy, including Thebesian valve coverage of the ostia. In this study, nearly 50% of Thebesian valves were moderately to severely obstructing the ostia. While studies have demonstrated identification of valvular anatomy via techniques such as endocardial direct visualization, no study to date has demonstrated an effective approach to CS cannulation when faced with difficult anatomy. Many conditions, such as atrial enlargement, structural heart disease, and prior cardiac surgery, often distort normal anatomy, leading to higher or lower than normal location of the CS ostium.

In addition, CS catheter placement from below may open the CS ostium to help guide access from above for low CS takeoff (Figure 1) and high CS takeoff (Figure 2). A temporary CS catheter may also subselectively cannulate the posterolateral branch (Figure 3). Taking out the CS catheter before tearing the guiding sheath did not cause any lead dislodgement. If we have difficulty in placing the CS catheter from below, we know that the anatomy is difficult and placing the LV lead from above will be challenging (Figure 4).

To our knowledge, there is no standard alternative means to access the CS once the superior approach has failed. Our study demonstrates the practicality of utilizing a novel approach for CS cannulation via the FV route. Although we demonstrated longer FT and PT times, this alternative technique should be considered as a viable alternative when the standard approach fails. In our experience, the CS was cannulated 100% of the time when utilizing the FV technique. Temporary access to the CS using a guide catheter via the FV warrants further investigation, as operators are able to develop more experience and improve proficiency.

**Conclusions**

In conclusion, the femoral vein approach as described represents a viable alternative for CS cannulation as in patients with difficult anatomy. An experienced operator may only utilize this approach perhaps once or twice a year; however, preparation of the groin may be helpful when an FV approach is being considered.
References


