Safety and Effectiveness of Placement of Pacemaker Leads for Cardiac Resynchronization Therapy in the Axillary Vein by Double Target-guided Venipuncture

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Background: The increasing incidence of damage to pacemaker leads for cardiac resynchronization therapy (CRT) is an emerging problem that should be prevented. The extrathoracic venipuncture approach has been suggested as a technique for venous access to avoid the problem. Methods and Results: 10 patients had pacemaker lead placement for CRT using the double target method. The lead was inserted in the extrathoracic portion of the subclavian and/or axillary veins without complications in all of the patients. Conclusion: This approach achieves accurate, safe, and speedy extrathoracic venipuncture and is especially suitable for multiple lead placements for CRT. (J Arrhythmia 2006; 22: 44–47)

Key words: Cardiac resynchronization therapy, Complication, Puncture, Extrathoracic subclavian vein, Axillary vein

Introduction

The infraclavicular subclavian approach has emerged as the method of choice for implanting endocardial pacemaker leads\(^1,2\) for cardiac resynchronization therapy (CRT).\(^3\) However, this approach results in an increased incidence of lead fracture due to entrapment of the lead by the costoclavicular ligament and the subclavius muscle (subclavian crush syndrome).\(^4,5\) Alternate techniques for lead placement have been proposed to minimize damage to the lead. The approach by surgical cut-down on the cephalic vein avoids lead damage,\(^6\) but the success of multiple lead placement for CRT depends on the diameter of the cephalic vein. If the cephalic vein is thin, multiple lead placement is difficult and requires an approach by venipuncture. The extrathoracic venipuncture approach was devised to overcome these difficulties and has the advantage of being more efficient for multiple lead placement than surgical cut-down. There have been no reports of failure with the extrathoracic approach for CRT or
that this method is time-consuming. However, it is thought that experience with this method is similar to that with conventional pacemaker lead placement. The purpose of this study was to evaluate the safety and efficacy of double target-guided extrathoracic venipuncture for CRT.

Methods

The study group consisted of 10 patients (4 women and 6 men, mean age 71 ± 5.7 years) who were referred for placement of a pacemaker for CRT. Informed consent was obtained from all patients. Five patients had coronary artery disease, 5 had nonischemic cardiomyopathy, and 2 had a previously implanted pacemaker. Ejection fraction was 27 ± 3.8%. All systems were implanted by an attending physician and a fellow. A total of 1 attending physician and 3 fellows were involved in lead placement during the course of this study.

Device implantation was performed in the electrophysiology laboratory. All devices were placed in a subcutaneous pocket created in the left infraclavicular region. Among the 10 patients undergoing pacemaker implantation, a new pacemaker for CRT was implanted in 8 and an upgrade to CRT was implanted in 2. In each patient, unipolar and bipolar pacing leads were used.

Each patient who participated in this study underwent an initial attempt at lead placement in the axillary vein utilizing the double target-guided method. The subclavian vein is entirely intrathoracic and extends from the take-off of the internal jugular vein to the take-off of the cephalic vein. The subclavian vein then becomes the axillary vein, which continues to the junction of the basilic and brachial veins. The axillary vein lies medial to, and partially overlaps, the axillary artery. Placement of leads via the axillary vein avoids entrapment by the subclavius muscle and the costoclavicular ligament, which have been implicated in causing lead failure.

Venipuncture was accomplished from within a typical subcutaneous pocket created parallel to and approximately 2 cm below the middle third of the clavicle. Double targets, which consisted of a pigtail catheter and a clip, were installed. The intravascular target was a pigtail catheter via femoral vein in the extrathoracic subclavian or axillary vein without heparin, which was positioned between the rib cage margin and the cross point of the clavicle and the first rib, and the extravascular target was a clip in the puncture point of the subcutaneous pocket. These targets were adjusted under fluoroscopy (anteroposterior view); the proximal margin of the clip overlapped the pigtail catheter (Figure 1A). The direction of venipuncture was determined by the overlapping

![Figure 1](image)

A: Double targets, which were a pigtail catheter and a clip, were adjusted under fluoroscopy (anteroposterior view); the proximal margin of the clip overlapped the pigtail catheter.
B: The direction of venipuncture was determined by the overlapping double targets (clip and pigtail) under fluoroscopy (left anterior oblique 45 degree).
C: The depth of the vessel was confirmed by the position of the pigtail catheter under fluoroscopy (right anterior oblique 30 degree).
D: The required of multiple lead placements, the pigtail catheter was moved and puncture was repeated.
double targets (clip and pigtail) under fluoroscopy (left anterior oblique 45 degree view) (Figure 1B). The depth of the vessel was confirmed by the position of the pigtail catheter under fluoroscopy (right anterior oblique 30 degree view) (Figure 1C). Under fluoroscopy, we punctured the double targets as the landmark. When multiple lead placement was required, the pigtail catheter was moved and puncture was repeated (Figure 1D). After successful extrathoracic venipuncture, guidewires were inserted and positioned in the superior vena cava under fluoroscopic control and these targets were taken off. The remainder of the procedure was carried out in the routine manner.

The safety and effectiveness of the double target-guided approach to the axillary vein described in this study were evaluated by comparing the results of five items that had already been reported for the contrast-guided approach\(^\text{12}\) with the results of the double target-guided approach in these 10 patients. The five items were rate of success of lead placement, required time for venipuncture (puncture to 1st lead insertion), number of venipuncture attempts, and the type and incidence of complications. Chest x-ray films were obtained the following day to rule out evidence of pneumothorax and to check the lead position. All patients were seen at 1 day, 1 month, and 6 months after the procedure to monitor for lead dislodgement, infection, hematoma, and any evidence of a subclavian and/or axillary vein thrombosis.

### Results

Between April 1, 2004 and January 31, 2005, 10 consecutive patients had pacemaker lead placement for CRT using the extrathoracic approach described above. The lead was inserted in the extrathoracic portion of the subclavian and/or axillary veins in all of the patients. The mean time required to obtain access to the axillary vein and to advance the leads to the heart was 16 ± 5 minutes. The average number of venipuncture attempts was 1.23 ± 0.39 per lead. There were no complications. No patient developed clinical evidence of venous thrombosis. In the two cases that required additional lead placement due to the upgrade to CRT, our technique could be performed by extrathoracic venipuncture without damaging the existing lead (Figure 2).

### Discussion

The subclavian crush syndrome has been reported as a drawback to the conventional infraclavicular subclavian approach for pacemaker lead placement. The surgical cut-down of the cephalic vein and the extrathoracic venipuncture approaches are the usual remedies to prevent this problem. In the development of therapies that require two or more placements of pacemaker leads for CRT, surgical cut-down of the cephalic vein alone might not be sufficient for multiple lead placements without venipuncture. It was reported that the extrathoracic subclavian and/or axillary approach had a lower
incidence of complications and prevented the subclavian crush syndrome; however, it had the disadvantage of occasional failure to puncture the vein. The objective of this study was to assess the safety and efficacy of the double target-guided approach for positioning pacemaker leads for CRT in the heart via the axillary vein. With this technique, lead placement was accomplished in all of the 10 patients.

Contrast-guided approach to axillary vein: Ramza and colleagues reported venipuncture performed from within the pocket by a needle positioned at a 60 degree angle to the plane of the skin and parallel to the axillary vein. The advantage of the contrast-guided approach to the axillary vein is its simplicity and ease. Furthermore, specialized imaging tools are not required. Despite the high efficacy and low incidence of complications associated with the contrast-guided approach to the axillary vein, several limitations must be recognized. First, as with any procedure involving contrast injection, there is a 1:40,000 to 1:100,000 incidence of an anaphylactic reaction. Second, while the course of the axillary vein is highlighted by contrast, vessel depth cannot be determined.

Double target-guided approach to axillary vein: This method has three useful characteristics. The first characteristic is a decrease in the number of punctures and, thus, a decrease in the complications that can accompany puncture. The second characteristic is the control of puncture points, angles and depth, which means that additional lead placements may be performed without damaging the existing leads. The third characteristic is multiple lead insertions within a short time. The disadvantage of the method is that it requires a pigtail catheter and a clip, but thrombotic complications have not occurred.

Table 1 shows data comparing previously reported results by the contrast-guided approach (pacemaker implantation for bradycardia and implantable cardioverter-defibrillator implantation) with results by the double target-guided approach (pacemaker implantation for CRT) for lead placement via the axillary vein. The rate of success of lead placement for the two approaches was equal. However, the time required for venipuncture was shorter and the number of venipuncture attempts was fewer with the double target-guided approach than with the contrast-guided approach. These results suggest that the double-target method should be selected in cases with renal dysfunction, contrast medium allergy or bleeding tendency, or when upgrade to CRT is required.

Conclusion

We described the double target method that can be used to install multiple leads with certainty, safety, and in a short time by the extrathoracic subclavian and/or axillary vein approach. This technique could employ extrathoracic venipuncture without damaging an existing lead.

References

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