Biventricular Pacing: A Simplified Implantation Technique

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Summary

Biventricular pacing is a promising therapy for patients with severe ventricular dysfunction and left bundle-branch block. However, the rate of unsuccessful procedures documented in the literature is still significant. The aim of this study was to assess the feasibility of using a new coronary sinus (CS) lead, the Corox LVS, for left ventricular pacing. Twenty patients (mean age 75 ± 9 years; 18 males) with severe heart failure (14 with a NYHA III classification and six with an NYHA IV), systolic dysfunction (ejection fraction < 35%), and left bundle-branch block (QRS > 140 ms) underwent biventricular pacing using the Corox LVS lead. In six patients the CS was approached using a preformed sheath that facilitated both lead insertion and a retrograde venogram. In 13 patients the CS was directly approached using the Corox LVS, in order to reduce implantation time. In one patient (6.3%), the CS could not be cannulated with any of the above-mentioned methods. Seven procedures resulted in an upgrade from conventional to biventricular pacing. The mean implantation time was 103 ± 45 min. The mean X-ray exposure time was 19 ± 9 min. The Corox LVS was placed in a posterolateral branch in eight patients, in a posterior branch in one patient, and in a lateral branch in 10 patients. The mean threshold value at implantation was 1.2 ± 1.0 V. No significant threshold increments were observed during follow-up (mean duration 83 ± 49 days). In one patient, an early lead displacement was observed and it was successfully repositioned. Two patients did not benefit from resynchronization therapy. In 17 patients, an improvement in the NYHA functional class was observed. All the patients showed a significant reduction in the QRS duration. The implantation of the Corox LVS lead appeared to be feasible and safe. Both approaches to the CS, using the sheath or the lead directly, were successful, but a significant reduction in fluoroscopy time (16.7 versus 26.5 min) was achieved using the direct approach. The rate of unsuccessful procedures (only one case) was low. Further investigations are required to confirm these findings in a larger population.

Key Words

Biventricular pacing, coronary sinus cannulation, fluoroscopy time

Introduction

The use of biventricular pacing in patients with advanced heart failure and intraventricular conduction delay has been associated with an improvement in hemodynamics, functional class, and quality of life [1-3]. More information is needed regarding the clinical and instrumental identification of responders to biventricular pacing as well as long-term monitoring of these patients. A positive response to biventricular pacing is genereally expected when electrical resynchronization is achieved [4]. Despite considerable technical improvement, mechanical problems related to the implantation procedure still exist.

Materials and Methods

Our study assessed the feasibility of using a new coronary sinus (CS) lead, the Corox LVS (Biotronik, Germany), for left ventricular pacing. The Corox LVS

Figure 1. Distal end of the Corox LVS coronary sinus lead (Biotronik, Germany).

(Figure 1) is a silicon insulated, unipolar lead with a soft, passive silicon tip (8.5 mm long, 3 French thick), aimed at improving the lead's self-guiding feature. An annular ring electrode with an Iridium fractal surface structure, proximal to the soft passive tip, performs the stimulation. The silicon beyond the ring electrode assumes a screw-like thread design for the fixation of the lead into a coronary vein. The distal part of the lead has a 4.35 French diameter and ends 8.5 cm from the tip. Between the distal part of the lead and the lead connector, a coaxial outer coil is situated, providing a stiffer support (lead body up to 6.6 French) and good maneuverability.

From May 2001 to November 2002, we enrolled 20 consecutive patients (mean age 75 ± 9 years, 18 males) who underwent biventricular pacing using the Corox LVS. All the patients had severe heart failure (14 had an NYHA class III, six had an NYHA class IV), despite maximal medical therapy. To be selected for implantation the patient had to have a left ventricular ejection fraction ≤ 35%. The ECG indicated a left bundle branch block, with an intrinsic QRS duration > 140 ms. In seven patients the procedure was an upgrade from conventional to biventricular pacing. In these patients the symptoms of heart failure were reasonably related to the left asynchrony induced by the right stimulation, with the ECG indicating a left branch block and a particularly wide QRS. The presence of left ventricular asynchrony was diagnosed by means of echocardiography. Five patients were in atrial fibrillation and two of these also underwent ablation of the atrio-ventricular node.

Two physicians performed the implantation procedures using local anesthesia. Patients were pre-medicated with atropine and received antibiotics prophylactically.

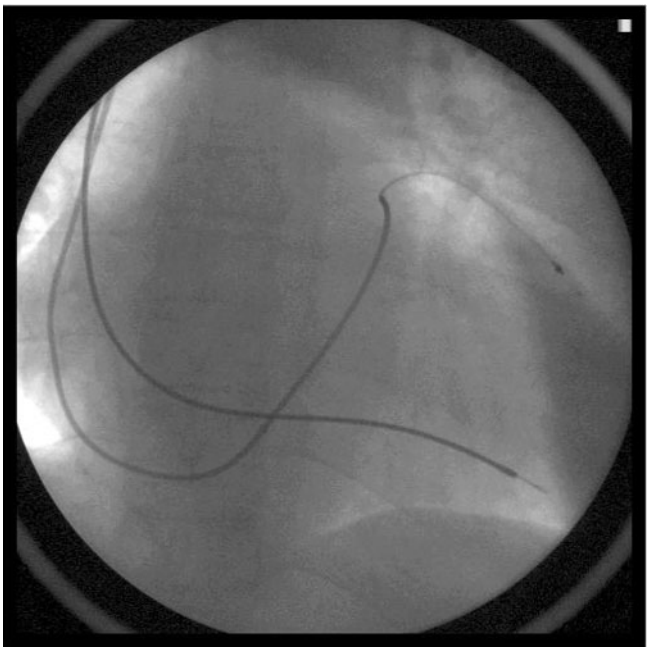

Figure 2. Fluoroscopic image (antero-posterior projection) after placement of the right and left ventricular leads.

For the lead placement the left subclavian vein and, whenever possible, the left cephalic vein were used. In one upgrading procedure, both the left cephalic and subclavian approaches were not feasible, and the right jugular vein was used instead. In the first six patients the SCOUT sheath catheter (Biotronik), available in two pre-formed curves, was used for CS cannulation. When necessary, the CS cannulation was facilitated by means of an electrophysiologic Josephson fixed curve or steerable curve catheter. The sheath enabled us to perform a selective retrograde occlusive venogram by means of a Swan Ganz catheter, and to place the lead in the preferred branch. In order to simplify the procedure and to reduce both implantation and fluoroscopy times, we tried to approach the CS directly using the Corox LVS lead in the last 14 patients.

After the placement of the right ventricular lead we manually preformed the stylet in order to place the tip of the lead toward the interatrial septum, and then, with torsion movements, the CS could be cannulated. Definitive position of the Corox LVS was established according to pacing and sensing parameters. When an anterior or anterolateral branch was reached, we decided to move the lead toward a lateral, posterolateral, or posterior branch. When the definitive position was achieved (Figure 2), a triple clockwise rotation of the

lead was performed to allow for better stabilization of the screw-like thread in the vein, while keeping the stylet fixed.

Results

In total, 19 procedures were successfully performed. In one patient (5%) we did not cannulate the CS, either with the direct approach, the sheath, or with a steerable electrophysiologic catheter. The mean implantation time (skin to skin time) was 103 ± 45 min. The mean X-ray exposure time was 19 ± 9 min. The Corox LVS lead was placed in a posterolateral branch in eight patients, in a posterior branch in one patient, and in a lateral branch in 10 patients. In the absence of the venogram the collateral branch was identified by means of fluoroscopic projections of the heart. The mean value of the left ventricular pacing threshold at implantation was 1.2 ± 1.0 V. No phrenic nerve stimulation occurred. No significant increments of the threshold were observed during the follow-up (mean duration 83 ± 49 days). In one patient (5.2%), we observed an early displacement of the lead that was successfully repositioned the following day. No significant complications were observed during the follow-up. Based on the clinical and echocardiographic follow-up, two patients (10.5%) were considered as non-responders to ventricular resynchronization. In 17 patients an improvement of at least one functional NYHA class was observed. All the patients showed a significant reduction in the QRS duration during biventricular pacing. A significant reduction in the fluoroscopy time using a direct approach compared to the guided approach was observed (16.7 ± 9.5 min versus 26.5 ± 6.4 min; p-value < 0.05).

Discussion

In the late 1990's, the early leads available for transvenous stimulation of the left ventricle through the CS were provided with an annular ring tip electrode and had a shaped configuration with a smaller diameter. The cannulation of the CS with pre-shaped guiding sheaths permitted both the introduction of the lead through the sheath, as well as CS angiography. The improvement in technological support and the increasing experience of physicians significantly reduced the rate of unsuccessful procedures. Nevertheless, the delivery of the therapy in an effective and minimally invasive way still presents some technical and methodological challenges. Currently, two types of leads for transvenous access to the CS are most popular: the over-the-wire system that includes a tined electrode with a central lumen, and an open tip for a wire-guided fixation. Other systems available are characterized by pre-shaped lead terminations that are available in many kinds of shapes and configurations to facilitate a passive fixation in the collateral veins.

The implantation success rate for the "over the wire" system [5] has been reported to be up to 83% with an implantation time from 1 to 8 hours (mean 169 min, depending on the physician's experience). A high number of electrode dislocations were reported during the first experience, and were later reduced to a rate of 2%. The recent data of the Miracle study [6] that included 228 patients in the pacing arm resulted in an 8% rate for unsuccessful implantations, and a rate of 2.6% for major complications (CS dissection, infections, shock, and two deaths). The mean implantation time was 2.7 hours and lead displacements were reported in 3.8% of cases. In other experiences [7], lead displacement was observed in 11% of patients even with more experienced physicians. The implantation success of these techniques strongly depends on the experience of the physicians and the rate of implantations per year at the pacing center. The mean fluoroscopy time for this procedure is reported to be about 45 min [7,8] even in centers with more experienced staff, but in many cases this time is significantly longer.

From the analysis of the literature it is evident that procedural aspects such as the difficulty to cannulate the CS, lead placement in the collateral veins, long X-ray exposure and total implantation times, as well as the stability of the lead and the frequent occurrence of phrenic nerve stimulation, are still problems requiring further research. Moreover, patients requiring biventricular pacing are frequently hemodynamically unstable and the procedure can easily exacerbate congestive heart failure and other major complications. In our experience the implantation of the Corox LVS lead for biventricular pacing appeared to be feasible and safe. The fluoroscopy exposure and total implantation time were considerably low, particularly when compared to the published data. Approaching the CS, either using the SCOUT sheath or directly with the lead was successful. Nevertheless, the direct procedure appeared to be simpler and more practical. This aspect could be particularly important in order to facilitate the implan-

tation procedure in hemodynamically unstable patients, as usually occurs in clinical practice with biventricular pacing. In any case we prefer to approach the CS directly with the lead, maintaining the possibility of using a guided approach as a second option. This technique seems to significantly simplify the procedure with a success rate at least comparable to other systems, without giving up the opportunity to pace an effective site in the left ventricle, in spite of the absence of a guiding venogram for the CS. The rate of unsuccessful procedures (only one case) appeared to be relatively low.

In conclusion, the procedure of biventricular pacing using the Corox system appears to be note-worthy based on its feasibility and low complications rate. Further investigations are required to confirm these findings in a larger population.

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