A randomized evaluation of different approaches to coronary sinus venography during biventricular pacemaker implants

Giuseppe De Martino*, Loredana Messano, Matteo Santamaria, Quintino Parisi, Antonio Dello Russo, Gemma Pelargonio, Tommaso Sanna, Maria Lucia Narducci, Tiziana Chiriaco, Fulvio Bellocci, Paolo Zecchi, Filippo Crea

Institute of Cardiology, Department of Cardiovascular Medicine, Catholic University of the Sacred Heart, Rome, Italy

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KEYWORDS
cardiac resynchronization therapy; coronary sinus venography; biventricular pacemaker implantation technique; biventricular pacing

Abstract
Aim Biventricular implantation procedures require contrast venography of the coronary sinus. The aim of our study was to evaluate the efficacy and safety of contrast venography obtained by direct manual contrast injection into the guiding catheter, compared with venography obtained after occlusion of the coronary sinus by a Swan–Ganz catheter.

Methods Eighty-three patients were randomly assigned to direct or occlusive venography technique. The primary endpoint was complication rate. The secondary endpoints were rate of and time required for an adequate venography, total dose of contrast medium and total procedure time.

Results Four dissections of the coronary sinus were observed with the occlusive venography technique group while no complications were observed with the direct venography technique group (p = 0.04). Rate of adequate venography was similar in the two groups (p = NS). The time needed for coronary sinus venography and the total dose of contrast medium was significantly lower in the direct venography technique group compared with the alternative (p < 0.0001 and p = 0.003, respectively); the total procedure time was not significantly different between the two groups (p = NS).
Conclusions

The direct venography technique shows a significantly lower incidence of complications and should be considered to be the first line approach to coronary sinus venography during biventricular pacemaker implantation.

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Introduction

Biventricular pacing is increasingly recognized as an effective therapeutic option to improve exercise tolerance and quality of life in patients with left ventricular systolic dysfunction, inter- or intraventricular conduction dyssynchrony and heart failure despite optimal medical treatment [1]. The transvenous approach is the most widely used with a guiding catheter advanced in the right atrium to achieve coronary sinus (CS) cannulation. Contrast venography of CS is then obtained, in order to define the anatomy including its branches and to select the optimal target vein, usually a posterolateral or lateral vein. Contrast venography can be obtained either by direct manual injection of contrast medium into the guiding catheter (direct venography technique, DVT) or after CS occlusion by a Swan–Ganz catheter (occlusive venography technique, OVT) (Fig. 1a and 1b).

Aim of the present study was to evaluate efficacy and safety of the DVT compared with the OVT.

Methods

Patients

Eighty-three patients with left ventricular dysfunction, intraventricular conduction delay (QRS duration > 120 ms) and symptomatic heart failure (NYHA functional class III or IV) despite optimal medical treatment were enrolled in the study. Informed consent was obtained in all cases. The clinical and echocardiographic characteristics of the two groups are summarized in Table 1.

Study protocol

CS cannulation was achieved as previously described [2]. Briefly, an electrode catheter was advanced inside the guiding catheter such to protrude 10 cm outside its distal end and then inserted inside the subclavian sheath. As the CS was cannulated with the protruding distal tip of the electrode catheter, the guiding catheter was advanced inside the CS over the electrode catheter.

Figure 1  An example (in the same patient) of contrast venography obtained by: (a) direct manual contrast injection into the guiding catheter (direct venography technique, DVT) and (b) occlusion of coronary sinus by a Swan–Ganz catheter (occlusive venography technique, OVT).
The electrode catheter was then withdrawn, leaving the guiding catheter in place.

After CS catheterization, patients were randomly assigned to DVT or OVT using a computer generated random numbers series.

The primary endpoint was complication rate. Secondary endpoints were achievement rate of adequate venography of the CS, time required for CS venography, total dose of the contrast medium and total procedure time. Venography was adequate if it allowed visualization of the CS both for its ostium and the course of its main tributaries. Complications were defined as procedure-related events requiring additional diagnostic procedures or treatments, prolongation of hospitalization or death. All implants were performed using a separate left subclavian access for right atrial, right ventricular and left ventricular leads. The MP 7300 and MP 6717 (Guidant Inc., St. Paul, MN, USA) 8 French guiding catheters and the non-deflectable decapolar electrode catheter CLS 2-8-2 (St. Jude Medical, Daig Division Inc., Minnetonka, MN, USA) were used in all patients.

In the DVT group CS venography was obtained by direct manual injection of contrast medium into the guiding catheter (as illustrated in Fig. 1a); in the OVT group, venography was obtained after CS occlusion using a 6 French Swan—Ganz catheter (Guidant Inc., St. Paul, MN, USA) which was advanced through the guiding catheter; the balloon was inflated with 1–1.5 ml of air immediately beyond the distal tip of the guiding catheter (as illustrated in Fig. 1b). All efforts were made to obtain a coaxial position of the catheters in relation to the CS and a test injection was performed in all cases before venography. In case of inadequate visualization of the venous system with DVT, failure was recorded on an intention to treat basis and crossover to OVT was allowed to permit procedure completion.

<table>
<thead>
<tr>
<th>Table 1 Clinical and echocardiographic data of the study population (mean ± standard deviation)</th>
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<td>Age</td>
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<td>LVEDD</td>
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<td>Diagnosis (%)</td>
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DVT: direct venography technique; OVT: occlusive venography technique; EF: ejection fraction; LVEDD: left ventricular end-diastolic diameter; CAD: coronary artery disease; DCM: dilated cardiomyopathy; CABG: coronary artery by-pass graft.

Statistical analysis

Normal distribution of continuous variables was assessed by Shapiro–Wilks test. Continuous variables showing normal distribution were compared by Student’s t-test for unpaired groups. Categorical variables were compared with χ-squared test or Fisher test as appropriate. Results are presented as mean ± standard deviation. A p value < 0.05 was considered significant.

Results

Eighty-three consecutive patients were randomly assigned to DVT or OVT. No differences were found between groups in baseline characteristics (Table 1). Successful catheterization of the CS was achieved in 82 out of 83 patients (98%).

Venography was rated adequate in 40 of 41 patients (97%) assigned to the OVT and in 37 of 41 patients (90%) assigned to DVT (p = NS). In the four cases of DVT failure a crossover to OVT venography allowed adequate visualization.

Four dissections of the proximal portion of the CS were observed in the OVT group (9%) while no complications were observed in the DVT group (p = 0.04). The course of CS dissection was uneventful and the implant was successfully completed without pericardial tamponade in all cases (Fig. 2a and 2b).

Time needed for CS venography was 6.4 ± 2.2 min in the OVT and 3.3 ± 1.5 min in the DVT (p < 0.0001); total dose of the contrast medium used was 35.2 ± 5.6 ml in the OVT and 31.5 ± 5.4 ml in the DVT (p = 0.003); total procedure time was 139 ± 34.6 min for the OVT and 128.7 ± 34.6 min for the DVT (p = NS). All the results are summarized in Table 2.

Discussion

The present study demonstrates that adequacy of angiography is similar with OVT and DVT techniques. Importantly, OVT is associated with a significantly higher risk of dissection of CS; it also required significantly longer venography time and more contrast medium.

A similar percentage of coronary dissection using the OVT has been reported by de Cock et al. [3] although lower rates of dissection have been described by other authors [4–7]. In de Cock’s series of 103 biventricular implants, seven CS dissections (7%) were observed using the OVT.
Although potential mechanisms of dissection proposed by these authors were inappropriate manipulation of the guiding catheter or of the pacing leads, the majority of dissections were located at the site of initial balloon inflation suggesting a major role of the Swan–Ganz catheter. Our data strongly support the hypothesis that the OVT is the major determinant of dissection during biventricular implant procedures. The stiffness of the Swan–Ganz catheter tip together with vessel wall trauma caused by balloon inflation are possible mechanisms of dissection.

In conclusion, our study shows that the DVT is associated with a significantly lower incidence of complications, at the same time allowing an adequate visualization of the coronary venous system comparable with that of the OVT, and should therefore be considered as first line approach to CS venography during implantation of biventricular pacemakers.

References


Table 2

<table>
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<th>DVT (n = 41)</th>
<th>OVT (n = 41)</th>
<th>p</th>
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<tr>
<td>Adequate venography (%)</td>
<td>37/41 (90)</td>
<td>40/41 (97)</td>
<td>NS</td>
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<tr>
<td>Dissections of CS (%)</td>
<td>0 (0)</td>
<td>4 (9)</td>
<td>0.04</td>
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<td>CS venography time (min)</td>
<td>3.3 ± 1.5</td>
<td>6.4 ± 2.2</td>
<td>0.0001</td>
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<tr>
<td>Contrast medium dose (ml)</td>
<td>31.5 ± 5.4</td>
<td>35.2 ± 5.6</td>
<td>0.003</td>
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<tr>
<td>Total procedure time (min)</td>
<td>128.7 ± 34.6</td>
<td>139 ± 34.6</td>
<td>NS</td>
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DVT: direct venography technique; OVT: occlusive venography technique; CS: coronary sinus.