Short and long-term single-centre experience with an S-shaped unipolar lead for left ventricular pacing

M. Fatemi, Y. Etienne, M. Gilard, J. Mansourati and J. J. Blanc

Department of Cardiology, Brest University Hospital, Brest, France

Left ventricular-based pacing is an established method for treatment of congestive heart failure in patients with ventricular dysynchrony. The transvenous epicardial approach is the method of choice to pace the left ventricle.

Aims To evaluate short and long-term stability and pacing and sensing performance of an S-shaped non-steroid unipolar lead.

Methods Forty-eight procedures were performed in 43 consecutive patients (mean age: 70 ± 8 years, 32 males) with severe congestive heart failure. The left ventricular lead was placed into a coronary sinus tributary. Pacing and sensing thresholds and pacing impedance were measured at implant, 1 and 6 months.

Results The mean procedure time was 90.0 ± 35.5 min. Pacing thresholds at implant, 1 and 6 months were 1.1 ± 0.8 V, 1.9 ± 1.3 V and 1.9 ± 1.5 V respectively. In 7 patients, lead implantation was unsuccessful. One of them had a successful second attempt. Lead revision was performed in 5 patients for loss of capture.

Conclusion The S-shaped unipolar lead evaluated in this study provides stable long-term position and pacing thresholds. Recent improvement of this S-shaped lead model will hopefully reduce the rate of implantation failures and acute dislodgements.

Key Words: Left ventricular pacing, congestive heart failure, lead implantation.

Introduction

Acute studies[1,2] and recent randomized clinical trials[3,4] have demonstrated that left ventricular pacing alone or in combination with right ventricular pacing is associated with acute haemodynamic benefit and chronic improvement in clinical status of patients having severe congestive heart failure, severe left ventricular systolic dysfunction and predominantly left ventricular conduction defects. Although transvenous pacing via the tributaries of the coronary sinus is currently considered as the method of choice to pace the left ventricle, preliminary experience with standard leads not specifically designed for this purpose was disappointing due to difficulties to reach the targeted area and frequent dislodgements[5]. Since then, considerable efforts were made to provide lead systems that could successfully navigate and chronically reside in the coronary venous system[6–8]. In the present paper, we report our short and long-term experience with a unipolar non-steroid-eluting S-shaped lead.

Patients and methods

Patients were selected if they met standard criteria for left ventricular-based pacing including end-stage heart failure with severe functional impairment (NYHA functional class III or IV) refractory to standard medical therapy, dilated ischaemic or non-ischaemic cardiomyopathy with left ventricular end-diastolic diameter ≥60 mm and left ventricular ejection fraction ≤0.35, and left bundle branch block with QRS duration >140 ms.

Technical aspects of lead and device implantation were described in detail in a previous publication[6]. Briefly, the coronary sinus was cannulated from a subclavian entry site using a commercially available long peelable guiding sheath (Daig Corp., Minnetonka, MN, U.S.A.). We used a curved introducer (ALLIANCE®...
60 cm, Daig Corp. Minnetonka, MN, U.S.A.) for left subclavian approach and a straight one (SEAL-AWAY® CS 45 cm, Daig Corp. Minnetonka, MN, U.S.A.) for the right approach. A quadripolar 7-French 4-mm-tip steerable electrophysiological catheter (Daig Corp. Minneapolis, MN, U.S.A.) was introduced through the introducer as distally as possible. The guiding sheath was advanced along the electrode catheter which was then removed and the permanent pacing lead (AESCULA, 1055K St Jude, Minneapolis, MN, U.S.A.) was inserted. The AESCULA 1055K (Fig. 1) is a non-steroid 4.8-French unipolar silicone lead with an S-shaped tip at stylet removal and special lubricious coating for ease of passage through the introducer and the veins. Attempts were made to place the left ventricular lead in a lateral coronary vein where the latest local electrogram was recorded relative to the QRS onset (Fig. 2).

For each procedure, skin-to-skin implant duration and the time to place the lead in the final position and corresponding fluoroscopy times were precisely recorded by the technician.

All patients benefitted from standard AV synchronous pacemaker with left ventricular pacing alone except those who already had a permanent pacemaker with a pre-existing right ventricular lead and those in permanent atrial fibrillation in whom AV node ablation was performed prior to pacemaker implantation. In the latter cases, a biventricular pacing system was implanted.

Pacing and sensing thresholds were measured at implant and at one- and six-month follow-ups.

**Statistical analysis**

Values are expressed as mean ± standard deviation. Unpaired Student t-test was used for comparison of right and left approaches. For comparison of pacing thresholds at implant, one and six months we performed the analysis of variance using the Bonferroni procedure. A P value of <0.05 was considered to be statistically significant.

**Results**

Since 1999, 48 procedures were performed in 43 consecutive patients (32 males, mean age 70 ± 8 years) with end-stage heart failure and left bundle branch block. The right subclavian vein was used in 21 cases and the left in 27 cases. Skin-to-skin procedure duration and total fluoroscopy time were 90.0 ± 35.5 and 33.5 ± 22.6 min respectively. Mean procedure time to place the left ventricular lead was 42.9 ± 29 min and the corresponding fluoroscopy time was 26.9 ± 20.9 min. No significant difference was found between the left and right subclavian approaches in lead placement and fluoroscopy durations (Table 1). In 7 patients lead placement was unsuccessful: 1 patient developed ventricular fibrillation during attempts to cannulate the coronary sinus, and was successfully resuscitated. The second procedure was successful. In 1 patient, the coronary sinus could not be cannulated. In 1 patient no lateral coronary vein could be found. In 3 patients the lead was placed in a satisfactory position but early and repetitive dislodgements occurred before or during sheath removal and after several attempts the procedure was interrupted because of long fluoroscopy time. In 1 patient despite successful lead placement in a lateral coronary vein pacing thresholds were unacceptably high.

Early lead dislodgement occurred in 6 patients within hours following lead placement and required repositioning in 5 patients for loss of left ventricular capture at maximum pacing amplitude. Lead revision was successful in 4 patients. Diaphragmatic contraction occurred in 2 patients. In one case it was associated with lead dislodgement and a rise in pacing threshold that required lead revision. No late dislodgement was observed after the first 48 h (Fig. 3). Acute and long-term measurements are displayed in Table 2. Mean pacing...
threshold at 0.5 ms pulse duration was 1.1 ± 0.8 V at implant. It increased slightly at one month (1.9 ± 1.3 V) and remained stable at six months (1.9 ± 1.5) (Fig. 4).

Discussion
Although transvenous left ventricular pacing has been demonstrated to be a promising therapy for heart failure patients with severe left ventricular dysfunction and conduction disorders, technical difficulties to reach the optimal target areas have limited the widespread clinical adoption of this method. New lead systems have been manufactured to facilitate precise placement of electrodes at the supposedly beneficial sites on the left ventricle with the limitation of the unpredictable anatomy of coronary sinus tributaries[9].

In this paper we describe our single-centre experience with an S-shaped unipolar lead specifically designed for left ventricular pacing. Our implant success rate (86%) was comparable with values reported in previous series during the same period of time with other left ventricular dedicated lead systems[3,4,8,10]. One explanation for our implantation failures which could be specific to the lead system is that after a few minutes of manipulation, the disappearance of the lubricious coating of the lead considerably limited its manoeuvrability. This technical aspect could also explain the relatively high dislodgement rate (16%) as in some cases the lead could not be advanced to a sufficiently distal position and therefore it

Table 1  Comparison of procedure durations in right and left subclavian approaches

|                    | Right approach | Left approach | P     
|--------------------|----------------|---------------|-------
| Total procedure time (minutes) | 94.3 ± 33      | 87.3 ± 37     | 0.54  
| Total fluoroscopy time (minutes) | 36.0 ± 23      | 31.8 ± 23     | 0.57  
| Lead placement duration (minutes) | 42.2 ± 27      | 42.6 ± 31     | 0.95  
| Lead placement fluoroscopy time (minutes) | 28.8 ± 20      | 25.6 ± 22     | 0.64  

Figure 2  Right anterior oblique view of the heart. The left ventricular lead is placed distally into a lateral branch of the coronary sinus.
slipped out into the coronary sinus with heart movement. It should be stressed that all lead dislocations occurred within the first hours following the procedure and in the long-term follow-up no further dislodgement was observed. The preformed S-shape of the lead at stylet removal which offers the advantage of pressing the lead against the walls of relatively large calibre veins probably contributes to its long-term stability.

Our skin-to-skin procedure time was shorter than in other published series[3,7,8]. In fact, the learning curve of left ventricular pacing was already completed when the study began in our institution. On the other hand the limited maneuverability of the lead after a short period of time precluded long procedures. Unfortunately during the study period we used almost exclusively the 1055K for left ventricular pacing and our experience with other lead types was very limited, therefore no comparison could be made with other lead systems designed for this purpose.

Pacing thresholds at implant were higher than those usually observed for endocardial pacing but for epicardial transvenous left ventricular pacing they were in the range of values obtained in other series[5,7,8]. They were reasonably low at one month despite the non-steroid character of the lead system. The impact of steroid-elution in new lead generations remains to be evaluated by further studies. Very importantly pacing thresholds remained stable over the 6-month follow-up. The clinical consequence of this finding is that the use of this lead will not significantly reduce pacemaker longevity.

In conclusion, the AESCULA 1055K is a safe lead system to pace the left ventricle and provides stable long-term pacing thresholds with a low complication rate. A new bipolar lead system with the preserved S-shaped configuration (AESCULA LV 1055T, St Jude, Minneapolis, MN, U.S.A.) is currently under investigation. The AESCULA 1055T model also uses silicone insulation and similar lubricious coating but has an additional polyurethane sheath over its proximal portion which further lowers the coefficient of friction and adds pushability for left lead placements. Its

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**Table 2 Pacing and sensing measurements**

<table>
<thead>
<tr>
<th></th>
<th>Implant</th>
<th>1 month</th>
<th>6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pacing thresholds (V)</td>
<td>1·1 ± 0·8</td>
<td>1·9 ± 1·3V</td>
<td>1·8 ± 1·5</td>
</tr>
<tr>
<td>R wave amplitude (mV)</td>
<td>13·4 ± 8</td>
<td>8·0 ± 3·0</td>
<td>8·8 ± 3·0</td>
</tr>
<tr>
<td>Pacing impedance (Ω)</td>
<td>879 ± 230</td>
<td>579 ± 180</td>
<td>668 ± 232</td>
</tr>
</tbody>
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**Figure 3** Patient flow chart.

**Figure 4** Pacing thresholds (V) at 0·5-ms pulse duration.
increased size will hopefully provide more stability in larger veins.

References


