Selective-site pacing in paediatric patients: a new application of the Select Secure system

Francesco Cantù¹*, Paolo De Filippo¹, Fulvio Gabbarini², Adele Borghi¹, Roberta Brambilla¹, Paolo Ferrero¹, Jennifer Comisso³, Tiziana Marotta³, Alessandro De Luca³, and Antonello Gavazzi¹

¹Electrophysiology, Cardiovascular Department, Ospedali Riuniti di Bergamo, Largo Barozzi 1, 24128 Bergamo, Italy; ²Regina Margherita Children’s Hospital, Turin, Italy; and ³Medtronic Italia SpA, Milan, Italy

Received 19 December 2008; accepted after revision 10 February 2009; online publish-ahead-of-print 5 March 2009

Aims
The aim of this study was to evaluate the feasibility and reliability of selective-site pacing by means of a new lead system in a paediatric population. This lead system is composed of a 4.1 Fr, active-fixation lead and a steerable catheter that allows easy positioning in selective sites.

Methods and results
Thirty young patients (mean age 9.0 ± 4.5 years, range 2–16 years) received a single- (10) or dual- (20) chamber pacemaker. The 3830 lead was implanted successfully in the targeted chambers in all patients. The selective RV sites of pacing in 26 of the patients were: 18 mid-septum, 5 outflow tract, 1 low-septum, and 2 LEVO-RV-Apex. In all patients, an intracardiac loop was left in order to avoid stretching of the lead with growth. Mean follow-up duration was 11 ± 10 months. Atrial sensing and pacing thresholds were 3.2 ± 1.7 mV and 0.8 ± 0.6 V at 0.5 ms at implantation and 3.4 ± 2.1 mV and 0.6 ± 0.3 V at 0.5 ms at follow-up. Ventricular sensing and pacing thresholds were 12.1 ± 4.9 and 0.7 ± 0.4 V at 0.5 ms on implantation and 12.7 ± 6.1 mV and 0.8 ± 0.5 V at 0.5 ms at follow-up (P = NS). No adverse events were reported.

Conclusion
Select Secure is a promising system for selective-site pacing in children.

Keywords
Selective • Pacing • Paediatric • New • Lead

Introduction
Transvenous permanent cardiac pacing has become a frequently used therapeutic modality in children who are candidates for ‘stand-alone’ (i.e. not associated with cardiac surgery) pacemaker (PM) implantation. The shift from the epicardium to the endocardium as the preferential pacing site was driven by the high rate of complications related to epicardial pacing in the mid-long term.¹

In the last decade, the detrimental effect of right ventricular apical pacing has been highlighted by a series of studies in both animals and humans.² The negative continuum starts from an inhomogeneous and dysynchronous electrical activation of ventricles, leading to changes in myocardial architecture and left ventricular mechanical contractions.³ The concept of selective-site pacing was developed with the aim of preventing the negative continuum associated with ventricular apical pacing, and includes pacing from the septum, from the outflow tract, and from selective His bundle pacing.²–⁴ Few data are available about selective-site pacing in children, although the detrimental effect of right apical pacing may be relevant in this setting on account of the long duration of pacing, in most cases, the patient’s lifetime.⁵,⁶ A new lead has recently become available (Select Secure lead, Medtronic, Inc.) with a smaller diameter (4.1 Fr) and improved crush and creep resistance owing to its lumenless structure. These characteristics seem to be ideal for transvenous pacing in young patients. Recent evidences have shown that this new lead is safe and reliable, with a medium-term follow-up comparable with that of traditional leads.⁷–⁹

The aim of this study was to evaluate the feasibility and the safety of transvenous selective permanent pacing with the Select

* Corresponding author. Tel: +39 035 266594, Fax: +39 035 266826, Email: fcantu@ospedaliriuniti.bergamo.it

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Secure Lead system in paediatric patients (0–16 years), and in particular:

(i) to evaluate the implantation technique particularly with regard to the feasibility and reliability of creating an intracardiac loop in order to avoid tension on the pacing lead due to the growth of the patient;

(ii) to evaluate electrical performance on acute and medium-term follow-up when the lead is screwed into a selective mid-septal position according to the literature.\textsuperscript{10,11}

Study population
From September 2006 to September 2008, 30 young patients (16 males) with indications to permanent pacing underwent a transvenous PM implantation procedure. The mean age at implantation was 9.0 ± 4.5 years (range 2–16 years). Mean weight at implantation was 29.1 ± 13.6 kg. All patients fulfilled a class I or IIa indication for permanent pacing according to the AHA/ACC guidelines. The mean ejection fraction of the systemic ventricle was 58 ± 14.6%.

The electrical disturbances prompting implantation were: complete AV block in 20 patients (67%), I degree AV block with sick sinus syndrome in 1 patient (3%), I degree AV block and right bundle branch block in 1 patient (3%), II degree AV block with sick sinus syndrome in 1 patient (3%), long QT syndrome in 1 patient (3%), sick sinus syndrome in 3 patients (10%), II degree AV block in 2 patients (7%), and II AV block and paroxysmal III AV block in 1 patient (3%).

In 12 patients (40%), the procedure was the first PM implantation, whereas 3 (10%) patients underwent upgrading to a dual-chamber PM. In 15 patients (50%), failure of a previous epicardial pacing system was documented and prompted endocardial implantation. The patients’ cardiac history, age, and weight at enrolment are shown in Table 1.

<table>
<thead>
<tr>
<th>Patients</th>
<th>Age on enrolment</th>
<th>Cardiac history</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pt 1</td>
<td>5</td>
<td>CCAVB, congenital</td>
</tr>
<tr>
<td>Pt 2</td>
<td>15</td>
<td>CTGA + VSD (S/P double switch operation)</td>
</tr>
<tr>
<td>Pt 3</td>
<td>14</td>
<td>Complex LVOTO</td>
</tr>
<tr>
<td>Pt 4</td>
<td>8</td>
<td>Heart transplantation</td>
</tr>
<tr>
<td>Pt 5</td>
<td>10</td>
<td>CCAVB, congenital</td>
</tr>
<tr>
<td>Pt 6</td>
<td>15</td>
<td>S/P TF repair</td>
</tr>
<tr>
<td>Pt 7</td>
<td>6</td>
<td>(S/P mitral valve replacement)</td>
</tr>
<tr>
<td>Pt 8</td>
<td>4</td>
<td>CCAVB, congenital</td>
</tr>
<tr>
<td>Pt 9</td>
<td>9</td>
<td>TGA + VSD + CoAo</td>
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<tr>
<td>Pt 10</td>
<td>3</td>
<td>TGA (S/P switch operation)</td>
</tr>
<tr>
<td>Pt 11</td>
<td>13</td>
<td>TF</td>
</tr>
<tr>
<td>Pt 12</td>
<td>8</td>
<td>ASD ostium secundum</td>
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<tr>
<td>Pt 13</td>
<td>7</td>
<td>CCAVB, congenital</td>
</tr>
<tr>
<td>Pt 14</td>
<td>11</td>
<td>DORV + AVC</td>
</tr>
<tr>
<td>Pt 15</td>
<td>14</td>
<td>CCAVB, congenital + PVS</td>
</tr>
<tr>
<td>Pt 16</td>
<td>2</td>
<td>LQTS—SCNSA mutation</td>
</tr>
<tr>
<td>Pt 17</td>
<td>15</td>
<td>Shone syndrome and systemic hypertension</td>
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<tr>
<td>Pt 18</td>
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<td>Pt 19</td>
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<td>Double discordance: atrioventricular and ventriculoarterial</td>
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<tr>
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<td>14</td>
<td>CCAVB, congenital</td>
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<tr>
<td>Pt 21</td>
<td>16</td>
<td>TF</td>
</tr>
<tr>
<td>Pt 22</td>
<td>12</td>
<td>S/P multiple VSD closure parachute mitral valve</td>
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<tr>
<td>Pt 23</td>
<td>4</td>
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<td>Pt 24</td>
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<td>CTGA + VSD; S/P double switch operation, dextrocardia in SVS</td>
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<td>Pt 25</td>
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<td>Down syndrome; S/P AVC repair</td>
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<td>Pt 26</td>
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<td>Pt 27</td>
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<td>S/P repair</td>
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<tr>
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<td>S/P VSD repair</td>
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<td>Pt 29</td>
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<td>S/P VSD + IPS repair</td>
</tr>
<tr>
<td>Pt 30</td>
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<td>CCAVB, congenital</td>
</tr>
</tbody>
</table>

ASD, atrial septal defect; AVC, atrioventricular channel; CAVB, complete atrioventricular block; CoAo, coarctation of the aorta; CTGA, corrected transposition of the great arteries; DCM, dilated cardiomyopathy; DORV, double outlet right ventricle; LQTS, long QT syndrome; LVOTO, left ventricular outflow tract obstruction; PVS, pulmonary valve stenosis; SSS, sick sinus syndrome; TAPVD, total atrio-pulmonary venous drainage; TF, Tetralogy of Fallot; VSD, ventricular septal defect.
Methods

The procedure was performed under general anaesthesia. The target position for ventricular lead fixation, in patients without ventricular malposition, was the right ventricular mid-septum; in TGA patient, the lead was positioned aiming only at stability. Specifically, the C-zone of the ventricular septum according to the Karpawich classification was chosen as the target site of pacing whenever technically possible. Atrial lead position was not predefined, as large areas of scarring are typical in congenital heart disease patients who have undergone surgical correction. The Select Secure system is composed of a steroid eluting, bipolar, lumenless, non-retractable screw-in lead (model 3830, Medtronic, Inc.), delivered through a steerable catheter (Select Site, model C304S-59 cm or C304L-69 cm, Medtronic, Inc.) that is inserted by transcutaneous single or double puncture of the left subclavian vein (Figure 1). The target sites were identified by using AP, RAO, and LAO fluoroscopic projections. Once the intracardiac unipolar electrogram recorded by the helix had been checked, the lead was screwed into the selected position. The lead was first gently pulled to verify its stability, and then pushed forward to create a loop in the right atrium. The target atrial loop for right ventricular lead screwed into the mid-septum is depicted in Figure 2A. The course of the lead in the right atrium was checked in the RAO projection in order to accommodate the lead body in front of the crista terminalis. This technique was developed to prevent arrhythmias and dislodgement of the loop in the outflow tract, and the consequent interference with the pulmonary valve, as described by Berul et al.12 In the case of a dual-chamber PM, the loop of the right atrial lead was created parallel to the RV lead (Figure 2B).

An unwinding test was done by slowing pulling the lead from the PM pocket.

After the leads had been screwed into their target positions, sensing and pacing thresholds were recorded to check the electrical performance. Final pacing thresholds were recorded 15 min after the leads had been screwed in, since we observed an improvement in the electrical parameter over time due to the reduction of screwing injury.

Finally, the steerable catheters were removed and the leads were gently stitched to a muscle by means of a ligature. A final check of electrical performance was carried out by means of a model 2090 (Medtronic, Inc.) Pacing System Analyzer, and the final positions of the leads and their loops were recorded by using fluoroscopic images. All patients underwent follow-up examination in our outpatient PM clinic every 6 months after implantation, and clinical evaluation, electrical measurement, and chest X-ray were performed to assess the clinical status of patients and the unwinding of the loop.

Results

Thirty young patients were implanted with at least one Select Secure lead. Ten patients (34%) received a single-chamber PM, whereas 20 (66%) received a dual-chamber PM. A total of 48 Select Secure leads were implanted: 22 in an atrial position and 26 in a ventricular position. The mean fluoroscopy time was 13.36 ± 10.52 min and the total procedure time was 83 ± 25 min. No adverse events occurred during the implantation procedure. The atrial leads were positioned as follows: 10 leads were screwed into the inter-atrial septum, 1 lead into the left atrium, 7 into the right atrial free wall, 1 into the Bachmann bundle, and 2 into the appendage. The ventricular leads were positioned as follows: 18 in the C-zone of the RV septum, according to the Karpawich classification (target position), 5 in the outflow tract of the right ventricle (D-zone), 1 in the low septum (B-zone), and 2 in a levo-positioned right ventricle. No leads were placed
in the RV apex. In all 26 patients, an intracardiac loop for each lead was created as previously described (see Methods) to avoid tension on the RV lead due to the patient’s growth.

Acute atrial lead electrical performance showed a mean atrial pacing threshold of $0.8 \pm 0.6$ V at 0.5 ms, a mean sensing threshold of $3.2 \pm 1.7$ mV, and a mean impedance of $656 \pm 116$ Ω, whereas acute RV lead electrical measurements were: pacing threshold $0.7 \pm 0.4$ V at 0.5 ms, sensing threshold $12.1 \pm 4.9$ mV, and impedance $691 \pm 165$ Ω.

The mean duration of follow-up was $11 \pm 10$ months (range 1–31 months).

The electrical performance of the leads in individual patients is shown in Figure 3. All patients showed stable thresholds and sensing values in both the atrium and ventricle; no patient had a significantly increased threshold or reduced sensing value. No clinical signs or symptoms of vein occlusion, such as collateral venous circulation on the chest wall, were detected in the whole population.

During follow-up, the position and degree of loop unwinding during growth were checked radiographically every year. In five patients, we observed correct and predicted partial loop unwinding, and in one patient complete unwinding. In the latter case, the loop was recreated during a stand-alone femoral procedure by grasping the lead at the level of the superior cava vein and pulling it towards the atrium. In this 3-year-old patient, angiography of the subclavian vein revealed no sign of occlusion or narrowing.

**Discussion**

**Lead performance**

From an electrical point of view, the Select Secure lead system performed well, both acutely and at medium-term follow-up. The mean pacing threshold was <$1$ V at 0.5 ms in both the atrium and ventricle at follow-up ($11 \pm 10$ months) and no significant threshold elevation was recorded. Even in the patient in whom the loop unwound completely, pacing parameters remained stable before and after the revision procedure. From a mechanical point of view, no complication, crushing, or dislodgement was observed during follow-up.

**Selective-site pacing**

Selective-site pacing has been recently proposed by many authors in order to reduce the unfavourable effects of long-term right ventricular apical pacing, which may be particularly detrimental in the paediatric population. The two alternative sites for right ventricular pacing that have been tested in humans are Hisian and septal.

**Figure 3** Electrical performance of the catheters at baseline and at follow-up.
Although our group has considerable experience of selective (pure) His bundle pacing\(^4\) in adults, we use a septal pacing modality for our paediatric population, since long-term histopathological, electrical, and clinical data on selective His bundle pacing are still lacking. Moreover, most children who require a permanent PM have an infra-Hisian location of AV block, which prevents pacing of the His bundle in its proximal position.

In contrast, a septal position appears to be ideal in the young for two reasons. First, the thickness of the ventricular septum prevents perforation and consequent tamponade and, unlike the apex, guarantees good sensing and a low threshold. Secondly, in a paediatric population, it has been shown that septal pacing prevents the deterioration of ventricular performance associated with apical pacing, even when a single-chamber pacing mode is applied.\(^10\)

In spite of the loss of the atrial contribution, this beneficial effect is particularly valuable in a paediatric setting, as a single-chamber pacing modality is often chosen for smaller patients.

The C region of the septum, according to the Karpawich classification,\(^11\) was identified as the target pacing site in our study, since some preliminary data have suggested that this location is superior to others in terms of left ventricular performance.\(^11\) Moreover, the C position is optimal to create a loop in the right atrium.

The success rate of pacing in the C region was 75% (18 of 24 patients without ventricular malposition). In six patients, after failing to target the C-zone, the ventricular lead was screwed into a D (five patients) or B position. No differences in terms of electrical performance were observed among the different septal positions. The rate of success in achieving the chosen zone slightly improved as the number of procedures increased and the total procedural and fluoroscopic time decreased consistently with an expected learning curve.

**Loop creation and unwinding over time**

The main factor that differentiates an adult from a child as a PM recipient is growth. The progressive increase in the distance between the device and the heart chambers stretches leads, being eventually responsible for crushing. In children, an intracardial loop is commonly created in order to avoid strain on the lead as the patient grows.

*Figure 2* depicts the course of the loops created in atrial and ventricular leads in our population. Lead bodies are accommodated in the channel between the crista terminalis and tricuspid valve. A possible dislocation of the loop towards the pulmonary valve has been described,\(^12\) which may interfere with valve function. In our population, no prolapse was documented in patients in whom a chest X-ray was performed during follow-up. Combining a mid-septal position of the lead tip with the loop course proposed (in this study population) may prevent prolapse as the distance between the lead tip and the tricuspid valve is limited, thus avoiding prolapse of the lead oxbow.

**Risk of vein occlusion**

Venous occlusion is a recognized complication of transvenous endocardial pacing. Studies in adult patients have reported the incidence of obstruction to be as high as 30–45% with an average complete occlusion rate of 12% and 1–3% symptomatic occlusion rate.\(^13\, 14\)

In the literature, there are contrasting reports on venous occlusion in children. A small study on venous thrombosis in children found no significant thrombosis or narrowing in 19 paediatric patients with pacing leads. However, a more recent study by Figa et al.\(^15\) reported a 21% incidence of obstruction (either partial or complete) in children. Bar-Cohen et al.\(^16\) have shown that the incidence of venous occlusion in young children is similar to that seen in adults, and furthermore, that patient’s age, body size, and lead characteristics on implantation do not clearly predict venous occlusion. It is likely that with regard to venous obstruction, these factors interact with the degree of venous injury on implantation and with lead diameter. Although follow-up data on venous occlusion in our study population are not yet available, the trade-off of the Select Secure system appears acceptable using the subclavian approach. The effect on venous patency appears less predictable with different access (axillary or cephalic). Indeed, the potential increase in the risk of occlusion caused by the use of the Select Site catheter (8 Fr) is balanced by the small diameter of the lead body (4.1 Fr). In the only patients in whom the subclavian vein was checked, the vein was patent and showed no sign of stenosis.

**Limitations**

Our population encompass a quite heterogeneous spectrum of structural heart disease, presumably responsible for different patterns of activation and haemodynamic arrangements. These issues should be theoretically taken into account when choosing the proper site of stimulation. In this preliminary phase, we were most interested in the feasibility safety and mid-term reliability of this technique in this particular population; further studies aiming at anatomico-functional correlation are warranted in the future. Furthermore, although the lead demonstrated an excellent performance at 1 year, the observation is still too short in order to derive definite conclusion about the long-term follow-up.

**Conclusion**

Select Secure is a promising system for selective transvenous pacing in paediatric patients. At implantation, it enables the pacing site to be effectively selected and an intracardiac loop to be created in order to allow unwinding during patient growth. At mid-term follow-up, electrical and mechanical performance is optimal and may lengthen the longevity of devices by reducing battery drainage.

**Conflict of interest:** J.C., T.M. and A.D.L. are Medtronic employees.

**References**


