Safety and Performance of a System Specifically Designed for Selective Site Pacing

FRANCESCO ZANON, M.D.,* CARLA SVETLICH, M.D.,† ERALDO OCCHETTA, M.D.,‡ DOMENICO CATANZARITI, M.D.,§ FRANCESCO CANTÙ, M.D.,¶ LUIGI PADELETTI, M.D.,** MASSIMO SANTINI, M.D.,†† GAETANO SENATORE, M.D.,‡‡ JENNIFER COMISSO, M.S.,§§ ANNAMARIA VARBARO, M.S.,§§ ALESSANDRA DENARO, M.S.,§§ and ANTONIO SAGONE, M.D.¶¶

From the *Ospedale Santa Maria della Misericordia, Rovigo, Italy; †Osp. della Versilia—Lido di Camaiore, Italy; ‡A.O. Maggiore della Carita’, Novara, Italy; §P.O. S. Maria del Carmine—Rovereto, Italy; ¶Ospedali Riuniti—Bergamo, Italy; * *O.A. Careggi—Firenze, Italy; ‡‡A.C.O. S.Filippo Neri—Roma, Italy; ††A.P. O. Riunito—Ciriè, Italy; §§Medtronic Italia, Roma, Italy; and ¶¶Ospedale Sacco—Milano, Italy

Introduction: In the right ventricle, selective site pacing (SSP) has been shown to avoid detrimental hemodynamic effects induced by right ventricular apical pacing and, in the right atrium, to prevent the onset of atrial fibrillation and to slow down disease progression. The purpose of our multicenter observational study was to describe the use of a transvenous 4-French catheter-delivered lead for SSP in the clinical practice of a large number of centers.

Methods: We enrolled 574 patients in whom an implantable device was indicated. In all patients, SSP was achieved by using the Select Secure System™ (Medtronic Inc., Minneapolis, MN, USA).

Results: In 570 patients, the lead was successfully implanted. In 125 patients, atrial SSP was performed: in 75 (60%) the lead was placed in the interatrial septum, in 31 (25%) in the coronary sinus ostium, and in 19 (15%) in the Bachman bundle. Ventricular SSP was undertaken in 138 patients: in 105 (76%) the high septal right ventricular outflow tract (RVOT) position was paced, in seven (5%) the high free-wall RVOT, in 25 (18%) the low septal RVOT, and in one (1%) the low free-wall RVOT. In the remaining 307 patients, the His zone was paced: in 87 (28%) patients, direct His-bundle pacing and in 220 (72%) patients para-hisian pacing was achieved. Adequate pacing parameters and a lead-related complication rate of 2.6% were recorded during a follow-up of 20 ± 10 months.

Conclusions: Our results demonstrated that many sites, in the right atrium, in the right ventricle, and in His-bundle region, can be paced using the Select Secure System™. (PACE 2011; 34:339–347)

Pacing, atrium, ventricle, His bundle

Introduction
Owing to the relatively easy lead placement and proven stability and reliability, the right atrial appendage (RAA) and right ventricular apex (RVA) have become the standard sites for pacemaker lead implantation. However, many experimental studies and large clinical trials have shown that the abnormal conduction of ventricular paced depolarization may lead to impaired cardiac function, arrhythmias, increased morbidity, and even mortality.1–8 Similarly the RAA pacing results in intraatrial dyssynchrony, as reflected by prolonged P-wave duration, with potentially important implications for atrial arrhythmias and for atrial hemodynamic function.9,10

The proven detrimental effects of standard pacing have prompted the search for alternative sites.11,12

However, stylet-delivered pacing leads have not been specifically designed for selective site pacing (SSP), potentially making more challenging their effective placement at sites different from RAA and RVA. Therefore, new lead models and specific tools have been proposed as an alternative method to satisfy the clinical demand for effective SSP.13

The aim of our multicenter prospective observational study was to describe the use of the Select Secure System (Medtronic Inc., Minneapolis, MN, USA) in clinical practice of a large number of South European centers, reporting data about safety and electrical performances of this system while achieving SSP in the right atrium, right ventricle, and His-bundle area in a large population.
Methods

Patient Population

Patients receiving an implantable device according to the current ACC/AHA guidelines\textsuperscript{14} and one lead permanently implanted in a selective site, namely ventricular pacing areas other than the RVA and right atrial sites other than the RAA, were prospectively enrolled in this multicenter international observational study (Appendix). The decision to perform SSP was left to the discretion of the implanting physician, as well as the choice of the specific site to pace, according to the physician’s clinical experience and the patient’s characteristics: atrial septal pacing for prevention of atrial arrhythmias, right ventricular outflow tract (RVOT), or His-bundle area pacing for the prevention of adverse hemodynamic consequences of apical pacing. All patients provided written informed consent, as approved by the Ethical Committee of each institution, for data collection, data management, and analysis.

Patients were divided into three groups according to the location of the target SSP site. The “Atrial group” was composed of patients indicated to receive the atrial lead in the interatrial septum. The “Ventricular group” comprised patients candidated to receive the ventricular lead in the RVOT. The “His-bundle group” comprised patients indicated to be paced in the His-bundle area. In patients receiving a dual-chamber device, the second lead was placed in a traditional site (RVA in patients of the Atrial group, RAA in patients of the remaining two groups).

Implantation Procedure

In all patients one SSP site was attempted by means of the Select Secure System\textsuperscript{TM} (Medtronic Inc.); this consists of a pacing lead (model 3830) and a deflectable catheter specifically designed to reach any site in the right cardiac chambers. The pacing lead is lumenless, bipolar, active-fixation, and steroid-eluting; it is small (4.1 Fr) and has a 1:1 torque transfer, an iso-diametric body, and a tip-to-ring spacing of 9 mm. The steerable catheter used to deliver the lead to the target site comes in two different lengths and shapes in order to reach both atrial and ventricular sites better (Select Site, models C304-S59 and C304-L69, respectively, Medtronic Inc.).

Implantation procedures of atrial, ventricular, and His-bundle leads have been previously described.\textsuperscript{13,15,16} For patients in the His-bundle group, the decision to implant an additional RVA lead was left to the discretion of the implanting physician. In that case, an additional lead was placed as a backup in order to ensure ventricular pacing in the case of His lead malfunctioning or development of infra-hisian conduction block during follow-up. In this instance, patients received dual- or three-chamber devices (instead of the indicated single- or dual-chamber) programmed to deliver His-bundle pulses and noncapturing RVA pacing during the nonexcitable period.

This series includes all consecutive implantation procedures for SSP attempted with the Select Secure System\textsuperscript{TM} in the participating centers. As mentioned before, the choice of the specific target pacing site was left to physician decision: according to the study design, the implanting physicians had to preliminarily identify a target pacing area among RVOT, the His-bundle area, or the interatrial septum, and the implant was considered successful if the actual lead positioning matched with these definitions. The final position of the lead was retrospectively classified by the implanting physician and confirmed by a blind committee, by analyzing x-rays images and ECG recordings according to Lieberman’s and Deshmukh’s definitions.\textsuperscript{12,17}

According to these definitions, in the interatrial septum three areas were retrospectively identified: the interatrial septum (mid-septum), coronary sinus ostium, or Bachmann’s bundle.\textsuperscript{17} In the RVOT area, four segments were defined: high or low septal RVOT, high or low free-wall RVOT.\textsuperscript{17} In the His-bundle area, His-bundle or Para-hisian region were discriminated. In accordance with Deshmukh’s definition,\textsuperscript{12} direct His-bundle (DHB) pacing was confirmed by the implanting physician and a posteriori confirmed by the blind committee by verifying the electrocardiographic concordance of QRS and T-wave complexes between paced and spontaneous rhythm, the equivalence of the paced-ventricular and the His-ventricular interval, and the absence of QRS widening at lower pacing output. When these criteria were not fulfilled, even though fluoroscopic images indicated that the lead was positioned in the His-bundle area, the location was defined as Para-hisian (PH). PH pacing may result in DHB-like stimulation when pacing output is increased.\textsuperscript{16}

Data Collection

On implantation, a 12-lead electrocardiogram, left anterior oblique (LAO), and right anterior oblique (RAO) fluoroscopic projections, from 30° to 45°, were recorded. In addition, fluoroscopy time was collected, defined as total time recorded by the fluoroscopy machine during the whole procedure (from skin to skin). Data on the electrical performance of the lead were obtained through pacemaker telemetry and prospectively collected on implantation and during follow-up.
RESULTS FROM THE SELECT SECURE™ REGISTRY

examination at 3, 6, and 12 months, and yearly thereafter. In addition, on implantation and at each examination all lead-related complications were tracked. A lead-related complication was defined as an adverse event due to the presence or performance of the lead, and which was either resolved invasively or resulted directly in the death or serious injury of the patient, explantation of the device or termination of significant device function.

Statistical Analysis
Continuous data were expressed as means ± standard deviation and categorical data were expressed as absolute and relative frequencies. \( \chi^2 \) test or Fisher’s exact test was used to compare categorical variables within groups, while continuous data were analyzed by means of a t-test or a Mann-Whitney nonparametric test, according to the normality of distribution. Student’s t-test for Gaussian distributions or Wilcoxon’s nonparametric test was used to compare baseline and follow-up data.

Comparisons between follow-up data were made only for patients with at least 24 months of follow-up and data of all scheduled visits available, by using a generalized linear model for repeated measurements. In each group (Atrial group, Ventricular group, and His-bundle group), variations of each parameter (pacing threshold, sensing, and impedance) were tested pairwise between each follow-up and the previous one. A P-value < 0.05 was considered significant for all tests. All statistical analyses were performed by means of SPSS software (SPSS Inc., Chicago, IL, USA).

Table I.
Baseline Characteristics of the Patient Population

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Enrolled Patients</th>
<th>Atrial Group</th>
<th>Ventricular Group</th>
<th>His bundle Group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n = 574</td>
<td>n = 125</td>
<td>n = 138</td>
<td>N = 307</td>
</tr>
<tr>
<td>Male gender, n (%)</td>
<td>351 (61)</td>
<td>61 (49)</td>
<td>89 (64)</td>
<td>200 (65)</td>
</tr>
<tr>
<td>Age, years</td>
<td>70 ± 15</td>
<td>69 ± 13</td>
<td>68 ± 21</td>
<td>72 ± 12</td>
</tr>
<tr>
<td>Ischemic cardiomyopathy, n (%)</td>
<td>100 (17)</td>
<td>16 (13)</td>
<td>32 (23)</td>
<td>52 (17)</td>
</tr>
<tr>
<td>History of heart failure, n (%)</td>
<td>132 (23)</td>
<td>26 (21)</td>
<td>48 (35)</td>
<td>58 (19)</td>
</tr>
<tr>
<td>Sick sinus syndrome, n (%)</td>
<td>288 (50)</td>
<td>90 (72)</td>
<td>72 (52)</td>
<td>126 (41)</td>
</tr>
<tr>
<td>First-degree AV block, n (%)</td>
<td>93 (16)</td>
<td>19 (15)</td>
<td>28 (20)</td>
<td>46 (15)</td>
</tr>
<tr>
<td>Second-degree AV block, n (%)</td>
<td>121 (21)</td>
<td>6 (5)</td>
<td>29 (21)</td>
<td>86 (28)</td>
</tr>
<tr>
<td>Third-degree AV block, n (%)</td>
<td>82 (14)</td>
<td>5 (4)</td>
<td>28 (20)</td>
<td>49 (16)</td>
</tr>
<tr>
<td>Ventricular tachyarrhythmias, n (%)</td>
<td>53 (9)</td>
<td>16 (13)</td>
<td>22 (16)</td>
<td>15 (5)</td>
</tr>
<tr>
<td>Atrial tachyarrhythmias, n (%)</td>
<td>288 (50)</td>
<td>89 (71)</td>
<td>53 (38)</td>
<td>146 (47)</td>
</tr>
<tr>
<td>QRS duration, ms</td>
<td>104 ± 31</td>
<td>93 ± 23</td>
<td>103 ± 33</td>
<td>108 ± 21</td>
</tr>
<tr>
<td>LV ejection fraction, %</td>
<td>50 ± 13</td>
<td>50 ± 14</td>
<td>48 ± 16</td>
<td>51 ± 11</td>
</tr>
</tbody>
</table>

AV = atrioventricular; LV = left ventricular.

Results

Patient Population
From November 2003 to May 2008, 574 patients in whom an implantable device was indicated and SSP was attempted with the Select Secure System™ in the right atrium, in the right ventricle, or in the His-bundle area were enrolled in the South European & South American Select Secure Registry. The lead implantation was successful in 570 patients, the lead being screwed into the target selective site and confirmed by the blind committee; according to the above-mentioned definition, the Atrial group comprised 125 patients, the Ventricular group 138, and the His-bundle group 307. Overall, our patients received 68 single-chamber, 389 dual-chamber, and 83 biventricular pacemakers; the remaining 30 patients received a cardioverter defibrillator. The baseline characteristics of the patients are summarized in Table I.

A total of four (1%) implant failures were reported in the study. For the overall population, the total fluoroscopy time decreased as experience in approaching selective sites with the Select Secure System™ increased. Specifically, the mean fluoroscopy time after the first 25 procedures proved significantly shorter than that of the first five implantations (14.0 ± 9.8 minutes vs 20.6 ± 14.2 minutes P < 0.001). Overall, during a mean follow-up of 20 ± 10 months (range...
6–50 months), 15 lead-related complications were reported in 15 (2.6%) patients.

In the same period, a total of 22 patients died: 12 were noncardiac deaths, eight nonsudden cardiac death, and two sudden cardiac deaths.

**Atrial Group**

In the Atrial Group 125 of 126 (99.2%) leads were screwed in the interatrial septum, as declared before implant. In the remaining case, a lead dislodgement occurred during the procedure and the same 3830 lead was repositioned in the RAA, due to the impossibility to find a stable position in the interatrial septum.

According to Lieberman’s definitions, in 75 (65%) patients the lead was screwed into the middle interatrial septum, in 31 (25%) patients into the low septum near the coronary sinus ostium, and in 19 (15%) patients into the Bachmann bundle. The mean fluoroscopic time was 16 ± 11 minutes. Figure 1 shows 45° RAO and 45° LAO x-ray projections of a patient implanted with a dual-chamber pacemaker in which the atrial lead was positioned in the Bachmann bundle.

On implantation, we measured a mean pacing threshold lower than 1 V at 0.5 ms and a P-wave amplitude greater than 2 mV. The electrical performances did not change over 24 months of follow-up, except for a decrease in impedance on 6-month follow-up examination (Table II). Moreover, no differences in electrical parameters emerged among the three atrial pacing sites (all P > 0.05 vs previous examination).

During a mean follow-up of 17 ± 9 months, a lead dislodgement was reported in two (1.6%) patients of the Atrial group, in one case associated to Twiddler syndrome. In both cases, the lead was extracted and a traditional lead was implanted in the RAA.

### Table II

<table>
<thead>
<tr>
<th>Visit</th>
<th>Atrial Group N = 85</th>
<th>Ventricular Group N = 92</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pacing Threshold, V</td>
<td>R Wave, mV</td>
</tr>
<tr>
<td>Induction</td>
<td>0.8 ± 0.5</td>
<td>2.1 ± 1.4</td>
</tr>
<tr>
<td>6 months</td>
<td>0.8 ± 0.2</td>
<td>2.3 ± 0.8</td>
</tr>
<tr>
<td>12 months</td>
<td>0.7 ± 0.1</td>
<td>2.1 ± 0.2</td>
</tr>
<tr>
<td>24 months</td>
<td>0.9 ± 0.3</td>
<td>2.0 ± 0.5</td>
</tr>
</tbody>
</table>

Pacing threshold tested at 0.5 ms pulse duration; * = P-value < 0.05 versus previous examination.
RESULTS FROM THE SELECT SECURE™ REGISTRY

Figure 2. (A) 30° right anterior oblique (RAO) and (B) 30° left anterior oblique (LAO) fluoroscopic projections, showing the position of the active-fixation ventricular pacing lead at the low septal right ventricular outflow tract (low septal RVOT).

Ventricular Group

In 138 patients (97.9%) of the Ventricular Group, the implant was carried out with the ventricular lead successfully screwed in the RVOT, with a mean total fluoroscopic time of 19 ± 15 minutes. One patient experienced a mild perforation without hemodynamic consequences, so a traditional lead was implanted in RVA after the patient recovered. Two patients had an acute lead dislodgement; in one case the same ventricular lead was repositioned in the RVA, while in the other case it was replaced with a different model. No complications associated with the acute lead removal were reported.

A posteriori analysis confirmed that in 105 (76%) patients the lead was placed in the high septal RVOT position, in seven (5%) in the high free-wall RVOT, in 25 (18%) in the low septal RVOT, and in one (1%) in the low free-wall RVOT.

On implantation, mean pacing threshold was lower than 1 V at 0.5 ms and the R-wave amplitude was greater than 9 mV. At the 6-month follow-up examination, a significant decrease in pacing impedance was recorded, together with a slight increase in pacing threshold; thereafter, all parameters remained stable (Table II) in next follow-ups. As in the Atrial group, we did not observe any difference in electrical parameters among the four ventricular pacing locations (P > 0.05). During a mean follow-up of 22 ± 9 months, the threshold of the lead in the ventricle in one (0.7%) patient increased exceeding 5 V at 0.5 ms of pulse duration. As a consequence of this event, the pacing output was increased to the maximum value but no repositioning was performed.

His-Bundle Group

Pacing of the His-bundle area was attempted and achieved in 307 patients. According to Deshmukh’s et al. definition,12 in 87 (28%) patients DHB pacing was effectively performed, as confirmed by electrocardiogram and fluoroscopy images, while the PH pacing was obtained in the remaining 220 (72%) patients. Mean fluoroscopy times for DHB and PH lead implantation were comparable (15 ± 9 minutes and 18 ± 13 minutes, respectively, P = 0.199). In 126 patients (41%), an RVA lead was placed as a backup. Figure 3 shows 30° RAO and LAO fluoroscopic images captured immediately after implantation of a dual-chamber pacemaker in which the ventricular lead was positioned in the low RVOT.

On implantation, electrical parameters differed between DHB and PH pacing: DHB pacing resulted in a significantly higher threshold, lower sensed-wave amplitude (both P < 0.001), and higher impedance (P = 0.008) (Table III). At each scheduled follow-up, up to 24 months, pacing threshold and sensed-wave amplitude remained significantly different between the groups. However, except for the increase in pacing threshold and the decrease in impedance on 6-month follow-up examination, no changes were observed on intragroup comparison.

Twelve events occurred in patients in the His-bundle group during a mean follow-up of 20 ± 10 months; specifically, in five (5.7%) patients with a DHB lead and seven (3.2%) patients with a lead in the PH region.

In the five patients with DHB, the pacing threshold rose to above 5 V at 0.5 ms of pulse duration, and in two cases this increase was associated to a decrease in the sensed wave to below 2 mV. In two cases the lead was replaced, while in the remaining three patients the device was reprogrammed to a higher pacing
output. However, in one patient this setting caused premature battery depletion, with consequent pacemaker replacement after 1 year.

In patients with a PH lead, we recorded two dislodgements, one necessitating repositioning and one replacement, and five cases of pacing threshold increase. These last cases were managed by increasing the pacing output in two patients and by shifting pacing from the PH lead to the RVA backup lead in three patients.

In the three patients of the His-bundle group in which the lead was replaced, no complications due to lead extraction were reported.

**Discussion**

Our data demonstrated the feasibility and safety of atrial and ventricular SSP using a 4-Fr lumenless, catheter-delivered lead over a medium-term follow-up, thus confirming the initial results reported by Gammage and colleagues over a shorter follow-up in a smaller population paced from both selective and traditional sites.13

In the right atrium and in the right ventricle, different selective sites have effectively been paced using the Select Secure System™ with a low rate of lead-related complication at implant (respectively 0.8% and 2.1%) and during follow-up (1.6% and 0.7%). Direct His-bundle pacing resulted in inferior electrical parameters and in an increase of pacing threshold in five out of 86 cases.

The great amount of clinical evidences about detrimental effects of pacing at traditional sites (RVA and RAA) on synchronous ventricular and atrial activation, with negative consequences on cardiac and hemodynamic function, arrhythmias, morbidity, and even mortality, encouraged the search for alternative pacing sites.

In particular, SSP has been proposed on account of its potential benefits. In the ventricle,

---

**Table III.**

<table>
<thead>
<tr>
<th>Visit</th>
<th>Direct His-bundle Pacing N = 63</th>
<th>Para-Hisian Pacing N = 150</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pacing Threshold, V</td>
<td>Sensed Wave, mV</td>
</tr>
<tr>
<td>Implant</td>
<td>2.5 ± 2.3</td>
<td>3.4 ± 1.0</td>
</tr>
<tr>
<td>6 months</td>
<td>2.8 ± 2.8</td>
<td>4.8 ± 3.6</td>
</tr>
<tr>
<td>12 months</td>
<td>2.7 ± 2.8</td>
<td>4.6 ± 3.0</td>
</tr>
<tr>
<td>24 months</td>
<td>3.2 ± 2.9</td>
<td>5.8 ± 3.0</td>
</tr>
</tbody>
</table>

Pacing threshold tested at 0.5 ms pulse duration; * = P-value < 0.05 versus previous examination; † = P-value < 0.05 versus direct His-bundle pacing.
SSP is considered to allow more physiological activation and contraction, leading to less detrimental remodeling.\textsuperscript{11,21} In the atrium, pacing from sites other than the RAA has been chosen in order to improve intraatrial conduction and minimize dispersion of refractoriness, thereby possibly preventing atrial arrhythmia recurrences.\textsuperscript{22–24} Another site where the effects of pacing have recently started to be investigated is the His-bundle region. Indeed, in patients with normal distal His conduction, stimulation at this site has been hypothesized to maintain the physiological activation pattern.\textsuperscript{12,15,25–27}

Recently, new tools have been proposed as an alternative approach to standard stylet-driven screw-in leads to achieve effective SSP.\textsuperscript{13} Specifically, the Select Secure System\textsuperscript{TM} is a steerable catheter-delivered pacing lead, designed to reach any site in the right cardiac chambers.

Our findings showed in a large population that Select Secure System\textsuperscript{TM} is a useful and safe tool to perform SSP from several sites in the right atrium and ventricle. Except for four implantation failures, the lead was effectively implanted in a nontraditional site with procedure fluoroscopy times that decreased as experience in using the system increased. Over a mean follow-up of 20 months, the system proved to be reliable for SSP in the atrium and in the ventricle; two dislodgements were recorded and the electrical parameters remained stable up to 24 months, allowing satisfactory pacing delivery. In addition, in the two cases of lead extraction need during follow-up, no complications were associated with the removal of the lead. Our results on SSP in the atrial and ventricular sites compare favorably with those of the preliminary experience with Select Secure System\textsuperscript{TM}.\textsuperscript{13} In that study, a relatively high rate of complications was reported on 3-month follow-up examination, though this subsequently improved significantly as implanter experience increased and after revision of implantation technique recommendations. The better results reported in our series may be ascribed to the prestudy training sessions on the implantation technique held in our centers and to the improved design of the delivering catheter, the currently available version of which has a smaller diameter and a less traumatic tip. In our experience, no differences in electrical performances emerged among SSP sites in the atrium or in the ventricle.

Separate considerations have to be made for the His-bundle group. The results obtained in this group showed that permanent DHB and PH pacing can be achieved by means of the Select Secure System\textsuperscript{TM}, without adverse events during implantation, confirming previous findings.\textsuperscript{15,16,26}

However, we can confirm that the electrical parameters yielded by DHB pacing are inferior to those observed on pacing in the PH region and at the other selective sites in the ventricle. Since previous publications\textsuperscript{12,25} have shown higher thresholds recorded on DHB pacing through conventional screw-in leads, this issue seems associated to the fibrous structure of the His-bundle area located in-depth in the membranous septum instead of the type of the lead. Nonetheless, electrical parameters remained stable and satisfactory during follow-up in most of the patients in both the DHB and PH groups.

Over a medium-term follow-up of 20 months, a higher rate of threshold increase episodes was recorded in the His-bundle group than in the Ventricular group; in particular, the majority of these occurred in DHB patients and in three cases required surgical revision of the system. These events were not associated with adverse clinical consequences for the patients, but confirmed that permanent His-bundle pacing should be more carefully considered than standard pacing or SSP in the right ventricle. When DHB pacing is attempted, an RVA lead should be positioned as a backup in order to ensure ventricular pacing in all patients with complete heart block at implant or expected deterioration of the conduction system during follow-up, and, in each case, when electrical parameters are not optimal at implantation.

Future studies comparing the long-term clinical outcome of DHB or PH pacing are needed in order to confirm preliminary experiences\textsuperscript{15,25,26,28} and assess whether the additional risks associated with such approaches are acceptable. Moreover, the performances and the limitations of these techniques need to be compared to those of the other ventricular selective sites, in order to obtain a clear picture of the possible options for patients requiring continuous ventricular pacing support.

\textit{Limitations}

The present work describes the performance of the Select Secure System\textsuperscript{TM} in achieving SSP without making a comparison with preexisting stylet-based leads either in the ability to reach the target site or electrical performances. The adding value of this new tool can only be assessed through a randomized controlled study. Additional data, such as the number of attempts before successful positioning of the lead, were not considered and their analysis could have improved the description of the implantation procedure.
Conclusions
The present study showed that in a large population of patients with pacemaker indication the Select Secure System™ allowed safe and effective SSP in the right atrium, right ventricle, in Para-hisian region, and in 94.3% of patients permanently paced in the His-bundle. Electrical performance of the lead was proved to be stable during a medium-term follow-up. Future randomized studies are needed to compare long-term clinical outcome of pacing from different pacing sites in different populations.

Acknowledgments: The authors express their gratitude to Claudia Campo (Statistical Service Team, Medtronic Italy) and Alessio Marseglia (Clinical Information Support, Medtronic Italy) who played a pivotal role in data management.

References
8. The DAVID Trial Investigators. Dual-chamber pacing or ventricular backup pacing in patients with an implantable defibrillator: The dual-chamber and VVI implantable defibrillator (DAVID) trial. JAMA 2006; 296:1115–1123.

ZANON, ET AL.
Appendix

List of participating hospital centers and physicians:

F. Zanon, E. Baracca, G. Pastore, Ospedale S. Maria della Misericordia—Rovigo, Italy; E. Occhetta, M. Bortnik, A. O. Maggiore della Carita’—Novara, Italy; D. Catanzariti, G. Vergara, M. Maines, P. O. S. Maria del Carmine—Rovereto, Italy; C. Svetlich, Osp. della Versilia—Lido di Camaiore, Italy; F. Cantù, P. De Filippo, Ospedali Riuniti—Bergamo, Italy; L. Padeletti, A. Colella, A. O. Careggi—Firenze, Italy; A. Sagone, Ospedale L. Sacco—Milano, Italy; M. Santini, R. Ricci, S. Filippo Neri—Roma, Italy; G. Senatore, P. O. Riunito—Cirié; E. Lombardo, Villa Maria Eleonora—Palermo, Italy; A. Vincenti, Osp. S. Gerardo dei Tintori—Monza, Italy; S. Sangiorgio, Osp. Civile—Sesto S. Giovanni, Italy; A. Curnis, L. Bontempi, Spedali Civili—Brescia, Italy; F. Giraldi, P. Della Bella, centro Cardiologico Monzino—Milano, Italy; F. Solimene, Clinica Montevergine—Mercogliano, Italy; A. Pe-rucca, Osp. S. S. Trinita’—Borgomanero, Italy; P. Bertocchi, G. Mantovani, Osp. di Circolo—Desio, Italy; M. D’Aulerio, Ospedale San Biagio—Domodossola, Italy; R. Massa, G. Tola, SS. Antonio e Biagio—Alessandria, Italy; S. Rossi, Ospedale di Circolo—Saronno, Italy; D. Ortega, Clinica San Camilo—Buenos Aires, Argentina; D. Vaccari, A. O. Montebelluna, Italy; M. Tritto, G. Spadaccini, P. Moretti, Clinica Mater Domini—Castellanza, Italy; J. Leal, Osp. Univ. —Valme, Spain; G. Belotti, Azienda Ussl 13—Treviglio, Italy; A. Sorgato, Osp. S. Orsola—Brescia, Italy; A. Visconti, Ospedale Civile—Acqui Terme, Italy; S. Lombroso, Ospedale Civile—Busto Arsizio, Italy; O. Pensabene, Ospedale Villa Sofia—Palermo, Italy; C. Puntrello, Osp. S. Antonio Abate—Trapani, Italy; M. Di Sabato, Ospedale di Circolo—Merate, Italy; D. Ortega, Hospital Universitario Austral—Pilar, Argentina; E. De Ruvo, Policlinico Casilino—Roma, Italy; I. Caico, Osp. di Circolo—Varese, Italy; C. Vassanelli, G. Zanotto, L. Tomasi, Ospedale Civile Maggiore di Borgo Trento—Verona, Italy.