First experience with a new active fixation coronary sinus lead

H. Nägeli1*, M. Azizi2, S. Hashagen1, M.A. Castel3, and S. Behrens1

1 Medical Department, St Adolfstift, Hamburgerstr. 41, D-21465 Reinbek, Germany; 2 Department of Cardiology, Albertinenkrankenhaus, Hamburg, Germany; and 3 Hospital Clinic, Barcelona, Spain

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Aims Coronary sinus (CS) lead implantation is a technically challenging procedure owing to variable vein anatomy and a high dislocation rate. Therefore, CS lead technology has undergone evolutionary changes during the last 10 years. The mode of fixation has been a passive one up to now. We want to describe our first clinical experience with the newly available active fixation lead 4195 in terms of dislocation rate and stability of thresholds compared with conventional models.

Methods and results From 1999 to February 2007, we implanted 403 CS leads in 368 patients. Leads were categorized into three different groups on the basis of their fixation mechanism: straight (Easytrak I and Situs OTW; n = 54), curved (Attain 4193 and 4194, Corox, Aescula, Situs ULD; n = 308), and active (Attain 4195; n = 41). Operative and follow-up data were prospectively noted and checked for significance between groups during the first 3 months after implantation. Kaplan–Meier analysis of long-term lead function was also performed. Straight and curved CS leads suffered from significantly more dislocations compared with active fixation (P < 0.001). The active fixation lead (4195) has a stable threshold over time compared with a significant rise after 24 h and thereafter in straight (62%) and curved leads (20%). However, retraction of an active fixation CS lead may be a difficult issue as outlined in two cases requiring pullback of a 4195 lead owing to phrenic nerve stimulation (one unsuccessful despite vigorous traction).

Conclusion The active fixation lead 4195 using retention lobes yielded stable thresholds over time and seems to be superior to conventional leads in terms of dislocation. However, extraction may be a difficult or even impossible task.

Key words CRT; Pacing; New technology

Introduction Nowadays, cardiac resynchronization therapy (CRT) can be considered as a standard therapy and is increasingly used in the coexistence of heart failure and intra- or interventricular conduction delays.

However, a prerequisite of successful CRT, the implantation of a coronary sinus (CS) lead, is a technically challenging procedure owing to variable vein anatomies. Therefore, CS lead technology has undergone evolutionary changes during the past 10 years. The first leads to stimulate the left ventricle were epicardially placed, but soon the transvenous route was preferred owing to a lower overall complication rate. The first leads suitable for the CS in the mid-1990s were straight without additional implantation tools for CS cannulation. It was not surprising that the positioning capability and stability were unacceptable in many cases, limiting the success of therapy. With the introduction of special delivery sheaths and the so-called ‘over the wire technology’, the breakthrough of transvenous LV pacing becomes a reality. Cannulation of the CS ostium is now a routine procedure performed in a few minutes. The addition of steroid to the lead tip completed their development.

The earlier-mentioned technological advances simplified CS localization and lead positioning in the target vein, but lead stability remains problematic. Because no muscular trabeculae were found in the CS for anchoring of the lead, the tip has to be pushed as distal as possible in a wedge position. This position cannot be reached in several cases owing to small and tortuous anatomy, or unfortunately, phrenic nerve stimulation prohibited placement in that more or less stable position. Secondly, a distal wedge position is not necessarily good for haemodynamics because the right ventricular lead was too near. For this instance, preshaped leads (curved in one or more dimensions) were developed to give stability even in proximal positions and in bigger veins. However, the preshaped leads have a reduced but still a significant high dislocation rate of ~5–10%. To resolve this last problem, finally, an active fixation lead was developed.

In this report, we want for the first time to compare different CS lead types with this newly developed active...
fixation lead (4195) in terms of dislocation rate and stability of thresholds.

Methods

From 1999 to 2006, we implanted 403 CS leads in 368 patients. The following lead types were used: Attain 4193 (Medtronic Inc., Minneapolis, MN, USA), n = 143; Attain 4194 (Medtronic Inc.), n = 87; Attain 4195 (Medtronic Inc.), n = 41; Corox OTW up (Biotronik, Berlin, Germany), n = 45; Corox OTW bp (Biotronik), n = 17; Easytrak I [Boston Scientific (formerly Guidant Corp.), Indianapolis, IN, USA], n = 46; Aescula 1055K (St Jude Medical Inc., St Paul, MN, USA), n = 9; Situs OTW [Sorin Biomedica (formerly Ela medical), La Boursidiere, France], n = 8; Situs ULD 28D (Sorin Biomedica), n = 7. With the exception of the Aescula 1055K and the ULD28D, all of those were over-the-wire leads. Leads were categorized in regard to their fixation mechanism in three different groups: straight (Easytrak I, Situs OTW; n = 54), curved (Attain 4193 and 4194, Corox, Aescula, Situs UKD; n = 308), and active (Attain 4195; n = 41). Leads with less than five implants were not analyzed. One implanter (H.N.) was responsible for CS lead placement in the whole time period. The excess number of leads compared with patients was explained by the replacement or the additional implantation of CS leads in the case of malfunction. There were no significant differences in the pre-operative NYHA stage, LV ejection fraction, LV end-diastolic diameter, and underlying heart disease (ischaemic vs. non-ischemic) between the groups (data not shown).

Pacemaker or defibrillator implantations with CS leads were performed with standard techniques via left or right cephalic or subclavian veins. The percentage of pacemaker and defibrillators was equally distributed between groups. The right ventricular lead was routinely placed to the right ventricular apex. The CS ostium was routinely cannulated by introducer sheaths deployed by each company. CS angiography was then performed using a balloon catheter. Then a target vein was identified. The first choice was to implant in posterior (lateral) position; the second choice in (antero) lateral position. Overall success rate of implantation was 97%. Eleven of the 4195 leads were implanted after dislocation of conventional leads (4 × 4193, 3 × 4194, 4 × Corox); the others were implanted in a consecutive manner. The Attain StarFix 4195 lead could be directly compared with the 4193 lead in regard to its similar lead body. The difference is that only one distal curve was present and the lead was encased with a plastic sheath (push tubing) for fixation and lobe deployment. Placement in the target vein was performed using a guide wire and/or a stylet. The fixation mechanism was deployed by extending three sets of fixation lobes by advancing the push tubing around the lead body (Figure 1). Lead positioning and lobe deployment was visualized fluoroscopically with the help of four radiopaque marker rings (Figures 2 and 3). The 4195 lead was repositioned by releasing the locking sutures around the fixation sleeve, reversing the lobe deployment, and moving the lead as desired. Threshold measurements were performed by the programmer of each company by slowly decreasing the voltage at an impulse width of 0.5 ms until loss of capture in each chamber was detected. The last effective voltage was defined as the threshold.

Operative and follow-up data were prospectively noted and checked for significance between groups during the first 3 month of implantation by means of Student’s t-test for unmatched pairs.

Results

In Table 1, the perioperative characteristics of different lead types are shown. It could be seen that straight and curved CS leads had more dislocations or threshold increases >5 V/0.5 ms as a surrogate for dislocation compared with virtually zero dislocations of the active fixation 4195 lead. There was a trend of shorter implantation time, reduced fluoroscopy time, and less contrast media use in the case of the 4195 lead. However, owing to great variations, these results are not statistically significant. Despite being theoretically more problematic because of a stiffer lead body, the 4195 lead could obviously be placed faster by sparing intraoperative dislocations, for example, during sheath retraction (which did not occur with the 4195 lead in contrast to several intraoperative dislocations with other lead systems). The active fixation lead had a completely stable threshold over time compared with a significant rise after 24 h and thereafter (Table 2). In this regard, it is the only lead with non-significant threshold changes compared. When patient groups were collected according to the fixation mechanism (straight, curved, active) significant differences were found between active fixation (4195) and all other lead types (Table 3). The total time needed for implantation was significantly shorter for the active fixation lead group. Furthermore, straight and curved leads showed significant dislocation rates or threshold rises >5 V/0.5 ms of up to 11 and 8%, respectively (P < 0.01). Instability of the lead tip was unmasked by a typical
threshold increase of straight leads (+62%) and even in curved leads (22%). In this regard, no change in the 4195 lead thresholds reflected an absolute stability in the primary position.

One significant problem in two cases could be noted up to now in regard to our experience with the 4195 lead. In the first case (Patient 1), an 80-year-old patient with dilated cardiomyopathy experienced non-tolerable phrenic nerve stimulation from a posterolaterally positioned 4195 lead (Figure 2, left) when lying in left lateral body positions. This problem was not detected during high-output stimulation in the operation theatre. The threshold of the phrenic nerve and of LV was absolutely identical at 1 V and different impulse widths, hence reprogramming was not possible. It was decided not to make an early revision, but to wait and see for 4 weeks. The pacemaker was programmed to right ventricular pacing mode only. However, after 4 weeks nothing had changed but the patient’s heart failure status worsened and re-operation was scheduled. During this intervention, it was only possible to retract the middle of the three fixation lobes. This could be seen in Figure 2 (right) by the distance between the second and the third visualization rings. Retraction had to be performed with two expanded lobes against considerable resistance. Just before we wanted to change to an implantation of a second one, the lead made a jump to a more proximal position with a threshold of 0.5 V at 0.5 ms and no phrenic nerve stimulation up to 10 V (Figure 2, right). Luckily, no complications of this manoeuvre could be noted. In the second case (Patient 2, Figure 3), an almost identical problem with phrenic nerve stimulation occurred. However, after 4 weeks during operative revision, it was not possible to retract the fixation lobe, and pullback of the lead with manual traction was unsuccessful. A second 4195 lead was implanted in a posterolateral vein nearby, causing no phrenic stimulation, and the patient ended up with two CS leads.

Discussion

The most important goal when implanting a CRT system is to reach a stable LV lead position in a suitable CS tributary associated with a low capture threshold and no extracardiac stimulation. Furthermore, long-term stability of leads and thresholds has to be expected, but was not reached with standard leads up to now, which limits the overall success of the method. In our experience, straight CS leads showed a non-acceptable rise in threshold, and
curved leads remain with a considerable dislocation rate of overall up to 8% (Tables 1 and 3). The last result is striking because preshaped leads are considered to resolve the problem of dislocation.13–16 There are different approaches to overcome this problem.20 One working group suggested leaving a guide wire in place for CS lead stabilization.21 However, this could result in fragmentation and lead fracture over time as we could recently show.22 Other working groups secured CS leads with the placement of coronary stents besides the lead body.23,24 However, this method may also be very problematic when extraction becomes necessary.

A stability of 100% is reached in our series with the active fixation 4195 lead. In our experience with 41 implantations, we observed zero dislocations (Tables 1 and 3) and absolutely unchanged low threshold values (Table 2) over the first 3 months of observation. As only one implanter was responsible for CS lead placement over time, there should be not too much of a 'learning curve' effect in recording displacement rates. However, there is one major obstacle: although extraction of non-active CS leads may be performed without any problems in most experiences,25–28 extraction or even laceration of the CS occurs, but after several months or even years of implantation, everything would show different. In the second case, it was completely impossible to retract any of the lobes or the lead itself, and therefore it was left in place (Figure 3). In this case, the implantation of a second lead would not change the clinical course, but

### Table 1 Perioperative characteristics of different lead types

<table>
<thead>
<tr>
<th>Lead model</th>
<th>n</th>
<th>Implantation time (min)</th>
<th>Fluoroscopy time (min)</th>
<th>Contrast media (mL)</th>
<th>Macrodislocation or threshold &gt;5 V/0.5 ms at day 1, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attain 4193</td>
<td>143</td>
<td>94 ± 37</td>
<td>15.5 ± 10</td>
<td>48 ± 47</td>
<td>8 (5.6)</td>
</tr>
<tr>
<td>Attain 4194</td>
<td>87</td>
<td>97 ± 38</td>
<td>14 ± 10</td>
<td>40 ± 45</td>
<td>6 (6.8)</td>
</tr>
<tr>
<td>Attain 4195</td>
<td>41</td>
<td>79 ± 37</td>
<td>8 ± 6</td>
<td>38 ± 34</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Corox OTW up</td>
<td>45</td>
<td>123 ± 44</td>
<td>20 ± 12</td>
<td>87 ± 50</td>
<td>5 (11)</td>
</tr>
<tr>
<td>Corox OTW bp</td>
<td>17</td>
<td>94 ± 36</td>
<td>11 ± 6</td>
<td>39 ± 26</td>
<td>1 (5.5)</td>
</tr>
<tr>
<td>Easylak I</td>
<td>46</td>
<td>97 ± 31</td>
<td>15 ± 9</td>
<td>45 ± 25</td>
<td>7 (15)</td>
</tr>
<tr>
<td>Aescula 1055 K</td>
<td>9</td>
<td>117 ± 32</td>
<td>19 ± 8</td>
<td>50 ± 20</td>
<td>3 (33)</td>
</tr>
<tr>
<td>Situs OTW</td>
<td>8</td>
<td>141 ± 32</td>
<td>20 ± 8</td>
<td>109 ± 90</td>
<td>2 (25)</td>
</tr>
<tr>
<td>Situs ULD 28D</td>
<td>7</td>
<td>98 ± 37</td>
<td>17 ± 15</td>
<td>32 ± 14</td>
<td>1 (14)</td>
</tr>
<tr>
<td>Total/mean</td>
<td>403</td>
<td>98 ± 37</td>
<td>15.4 ± 10</td>
<td>55.2 ± 35</td>
<td>33 (8.5)</td>
</tr>
</tbody>
</table>

*P < 0.01 vs. implant.

<table>
<thead>
<tr>
<th>Fixation type</th>
<th>n</th>
<th>Op. time (min)</th>
<th>Flu. time (min)</th>
<th>KM (mL)</th>
<th>Dislocation/ threshold &gt;5 V (%)</th>
<th>Threshold rise day 1 vs. OP (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Straight</td>
<td>54</td>
<td>100 ± 35</td>
<td>16 ± 10</td>
<td>126 ± 60</td>
<td>11</td>
<td>62</td>
</tr>
<tr>
<td>Curved</td>
<td>308</td>
<td>100 ± 39</td>
<td>15 ± 10</td>
<td>55 ± 50</td>
<td>8</td>
<td>20</td>
</tr>
<tr>
<td>Active</td>
<td>41</td>
<td>77 ± 32*</td>
<td>8.0 ± 6.0*</td>
<td>35 ± 25*</td>
<td>0*</td>
<td>0*</td>
</tr>
</tbody>
</table>

Op. time, total duration of the intervention; Fluor time, duration of fluoroscopy. *P < 0.001 vs. straight and curved.
obviously there are situations (infection) where complete extraction of a lead is absolutely necessary. Open heart surgery or laser techniques would then be the only secure method for removal.

In conclusion, technical advances have improved the success rate and reduced procedural and fluoroscopic times for biventricular system implantation. An electrophysiologically guided approach makes cannulation of the CS a highly reproducible procedure that requires minimum fluoroscopic time.29,30 True active fixation, as it was the case with the 4195, will resolve problems with dislocations or threshold rise. Furthermore, active fixation may allow a better haemodynamic position, more distant from the right ventricular pacing lead. In regard to cost-effectiveness, active CS lead fixation may spare expensive redo operations compared with the other two groups.

However, retraction of an active fixation CS lead may be a difficult issue as outlined in our two cases and should lead, in our opinion, to restricting the use of active fixation in the CS for reoperations after previous dislocation. The commercially available 4195 should be preferred, in our opinion, against the earlier-mentioned uncommon techniques21,23,24 because lead fixation by wires or stents either may have specific problems such as lead fragmentation20,32 or will most likely result in difficult extraction procedures as well. Alternatively, minimally invasive epicardial techniques such as video-assisted thoracoscopic methods should be tested in controlled studies against transvenous approaches.31 That the active fixation of leads by a screw-in mechanism can safely be used for LV pacing has also to be shown.32,33

References