Ease of Handling with a Single Pass Lead Versus Atrial Tracking Functions: A Single Center Experience with the SOLOX VDD Lead

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Summary

Single pass leads are advantageous because they are easy to handle and require a short time for implantation. However, the disadvantages of these leads include the potential loss of tracking the atrial signal (due to its remote position from the atrial wall) and possible lead movements. In this study, a single pass lead (SOLOX SLX-65 BP) was implanted in 20 patients (age 77 ± 6 years; 14 f, 6 m). The average implantation time was 48 ± 11 min, and the time for (definitive) lead positioning was 8 ± 7 min. The number of attempted positions was 3.5 ± 2.9. One early dislocation was successfully repositioned. The R-wave was 11.9 ± 6.4 mV, and remained within that range. The ventricular pacing threshold and the impedance were 0.51 ± 0.18 V and 808 ± 107 Ohm, respectively. P-wave amplitudes and other measurements were done with an ERA 300, and the pacemaker telemetry with an ACTROS SLR. The results of the study show that the SOLOX lead can be implanted with ease and within a short time compared to a ventricular lead. The atrial signal is acceptable at the average level. However, the signal shows variations, which can still be sensed when the atrial sensitivity is programmed at a high range.

Key words

Single pass lead, implantation time, atrial tracking functions, pacemaker

Introduction

The conservation of AV synchrony after pacemaker implantation is important for tracking the atrial rate response as well as for hemodynamic reasons. This AV synchrony can be established with a dual-chamber pacemaker attached to two leads, or with just one lead - the single pass lead and a VDD(R) pacemaker. In short, the implanting cardiologist must decide between these two distinct systems. Is the choice a single pass electrode with a VDD pacemaker? The comparison with a DDD pacemaker focuses on the trade-off between a longer and more complicated implantation procedure versus tracking the atrium (via the atrial signal). The patient should have a normal sinus rhythm without sinus bradycardia, and preferably without retrograde (VA) conduction.

With a DDD pacemaker and two leads, the atrial lead will provide better sensing due to the tip's contact with the atrial wall; undersensing (and inappropriate pacing) occurs only in the case of dislocation. Atrial undersensing over the atrial dipole of single pass leads has been reported (with variable percentages) in large studies [3-6]. These early reports excluded information concerning the safety of remote sensing of the ventricles [7]. However, the undersensing of atrial events appeared to be a minor event during VDD pacing, as shown by external Holter monitoring. When it (temporarily) occurred, it did not provoke symptoms [8-10]. The complication rate of VDD pacemaker systems is comparable to a standard VVI pacemaker [6].

Few reports are available concerning implantation procedures and their ease of handling [4]. Therefore, a study was performed to evaluate the ease of implantation, the implantation procedure, and the time intervals in relation to the atrial tracking functions (Pwa) of the SOLOX single pass lead (Biotronik, Germany). The optimum goal was to reach good ventricular pacing thresholds and sensing values.

Demographic data		
Age	77 ± 6	yrs
Females	14	70 %
Males	6	30 %
Weight	71 ± 10	kg
Length	171 ± 5	cm
Underlying heart disease		
Coronary artery disease	4	20 %
Valvular heart disease	4	20 %
Hypertension	4	20 %
Chronic obstructive pulmonary disease	2	10 %

Table 1. Demographic data.

Methods and Patients

Twenty consecutive patients were enrolled in the study. Table 1 summarizes the demographic data. The mean age was 77 ± 6 years (range 62 - 85 years); there were 14 females and 6 males. All patients had experienced syncopal events and a total AV block without evidence of sinus bradycardia. Contraindications were patients with any of the following conditions: an inadequate atrial response rate, or chronic or persistent atrial flutter or fibrillation.

Implantation and Follow-Up

A standard implantation procedure was performed. The lead was routinely introduced into the subclavian vein. The cephalic vein was used only in cases of poor access to the subclavian vein. After introduction of the single pass lead, the tip was positioned into the right ventricular apex and the pacing and sensing functions were tested, followed by the atrial sensing functions. In case of an unstable ventricular position, poor ventricular pacing or sensing characteristics, or poor atrial sensing values, the lead was retracted from its position and a new position was found. Stability of the ventricular position and ventricular pacing and sensing characteristics were prevalent over the atrial sensing values. The lead's position was documented on X-ray in the antero-posterior view; sometimes it was documented in the lateral view as well (Figures 1a and b). On the day after implantation, X-rays were taken to document the lead position and to rule out a pneumothorax. During implantation, the ERA 300 (Biotronik) pacing system analyzer was used; this device has filtering characteristics similar to the implanted pacemaker (Actros SLR, Biotronik).
Ventricular sensing values in the form of R-waves were measured; the pacing threshold and impedance were measured at 4.8 V.

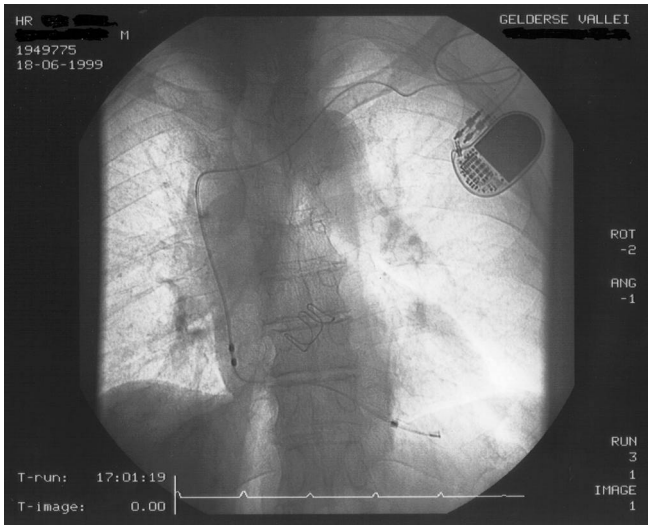

Figure 1a. Antero-posterior X-ray of the implantation. Note the slack in the single pass lead and the position of the atrial dipole in high-mid level of the right atrium, and the stent of the valvular aortic prothesis.

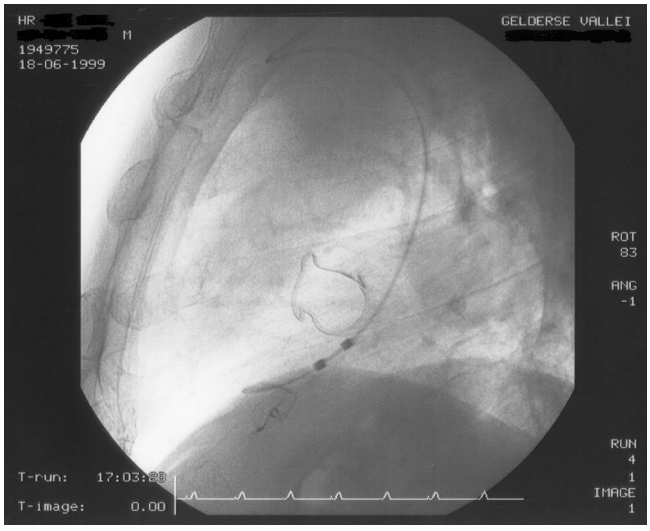

Figure 1b. Lateral view of the same patient during implantation.

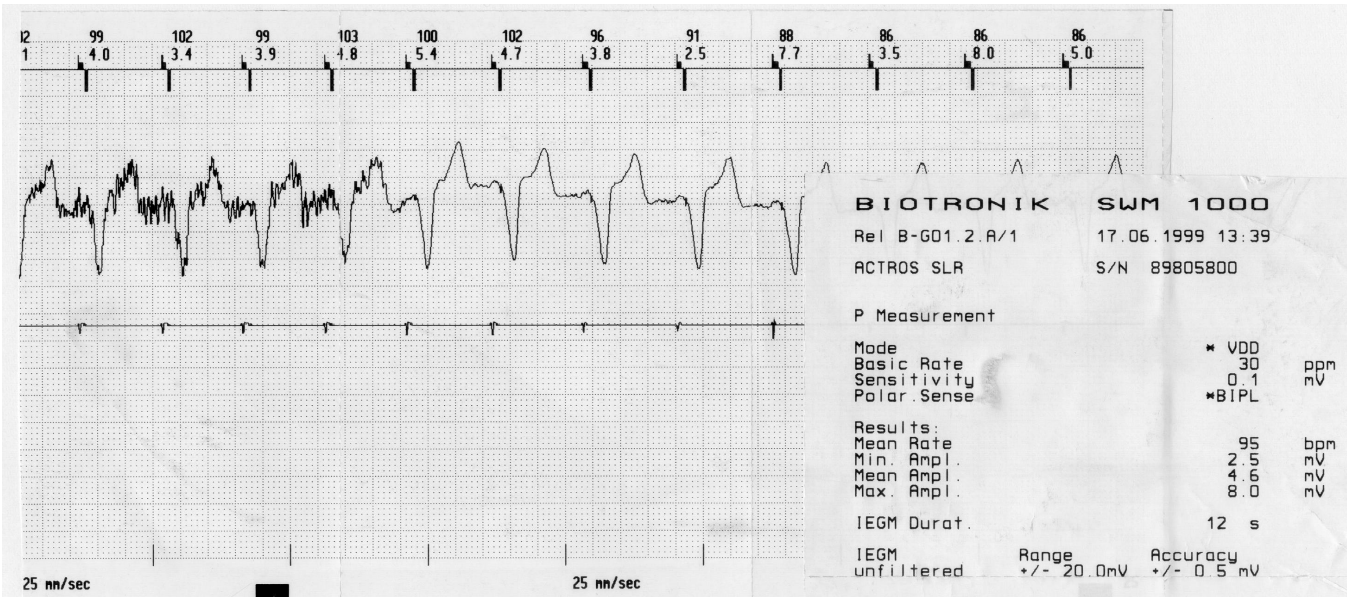

Figure 2. A printout of the atrial sensing test with the Actros SLR and Biotronik programmer PMS 1000. Each atrial beat is sensed, and the P-wave amplitude is displayed above the P-wave. The number above the P-wave value is the calculated rate. In the printout (lower right), the minimum, mean, and maximum amplitudes are given.

A patient follow-up was performed at regular intervals. Upon discharge from the hospital, patients were seen at one-month (± 1 week), three-month (± 2 weeks), six-month (± 4 weeks) and twelve-month (± 4 weeks) intervals.

The Actros pacemaker generates a report with minimum, mean, and maximum values (see Figure 2). To assess the sensing values of the single pass lead, the pacemaker measures all values provided over a period of 12 sec. The number of measured P-waves is then dependent on the spontaneous (sinus) rate, but in general one measurement contains 16 beats. In our study, the P-wave measurements were variable.

Device Description

The SOLOX single lead is a quadripolar passive fixation VDD device. It has a small 3.5 mm^2 electrode tip; the ring electrodes have a geometrical surface of 25.4 mm^2. All electrodes are covered with a fractal iridium structure. The fractal structure provides an extremely large active surface area, which in turn ensures an excellent charge transfer between the electrode and the myocardium. Iridium is a very biocompatible material; in conjunction with the fractal structure, it results in excellent sensing values and low pacing thresholds.

The lead body, insulated with silicone, has a diameter of 2.5 mm which requires a 9-French introducer. The overall length of the lead is 650 mm. There are five versions with different tip-to-ring distances (atrium) available: 11, 13, 14, 15, and 17 cm. The distance between the atrial rings is 10 mm, and the distance between the tip and the ventricular ring is 31 mm (see Figure 1). The lead tip has three tines. The SOLOX lead has been improved considerably compared with the older versions such as the SL-BP. The SOLOX is thinner and has better handling behavior. The distal portion is less prone to kinking due to its lighter weight and more homogenous transition from the lead body to the distal tip. The stronger tines may reduce the risk of dislocation. Last, but not least, the lead impedance has been increased by production of a smaller tip surface, which is identical to that of the Polyrox lead. Moreover, compared to other leads, the ohmic resistance is largely reduced (1.14 to 0.3 Ohm/cm) due to the use of cables as conductors. There is only one coil remaining to accommodate the stylet.

Results

The implantation procedure was successful with only one minor side effect that was quickly resolved. In one patient, an early dislocation (before closure of the pocket) was observed with subsequent successful repo-

Implantation data	Mean ± sd	Range	
Total implantation time (skin to skin)	47.9 ± 10.6	31 – 73	min
Time from insertion to final position	8.05 ± 7.03	2 – 30	min
Number of positions	3.40 ± 2.93	1 – 13	

Table 2. Implantation data.

sitioning of the electrode. Table 2 provides implantation data. In nine patients, the lead distance (from atrial dipole to ventricular tip) was 13 cm, and in 11 patients it was 15 cm. Three patients died during the follow-up period, two within three months and one within 6 months. These deaths were not related to either the single pass lead or the pacemaker.

The pacing and sensing characteristics of the ventricular electrode are given in Table 3. In three patients, no escape rhythm was present at the time of implantation, and the R-wave amplitude could not be measured. In some instances, there were minor problems threading the lead through the superior vena cava and through the tricuspid valve. However, this did not have an overall effect on the implantation time (insertion in vessel to final position). The exact time for positioning the lead (once it was introduced into the right ventricle) and the number of positions cannot be given. In one patient, the implantation was performed on the right side. Therefore, there were no problems maneuvering the introducer from the right subclavian vein into the superior vena cava. The pacing impedance measured during implantation (808 ± 187 Ohm) was different from the pre-discharge levels (564 ± 94 Ohm); this may have been related to the measuring device. During follow-up, the pacing impedance did not change very much; at 1 month it was 564 ± 119 Ohm and at 3 months it was 642 ± 129 Ohm. The ventricular pacing thresholds over time are depicted in Figure 3. The ventricular threshold is always measured at 0.5 pulse width. There was a small

	Mean ± sd	Range	Units
R-wave	11.9 ± 6.43	3.2 - 22	mV
Ventricular threshold	0.51 ± 0.18	0.3 - 1.0	V
Pacing impedance	808 ± 187	548 - 1156	Ohm

Table 3. Pacing and sensing characteristics of the ventricular electrode.

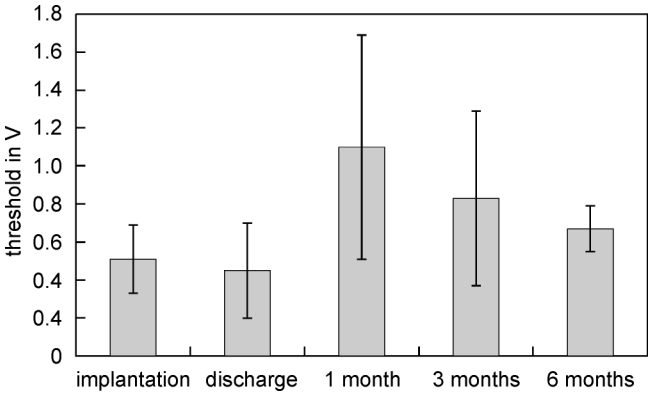

Figure 3. Ventricular pacing threshold with the mean and one standard deviation. The measuring points are at implantation, discharge (days 2 - 4), 1 month, 3 months, and 6 months, respectively. The increase and subsequent leveling off values (until implantation) are clearly noticeable.

decrease between implantation and pre-discharge, and subsequently an increase with a maximum at 1 month followed by a decrease at 6 months until just above the values at implantation: 0.67 ± 0.12 V at 6 months.

The P-wave amplitudes were measured as scheduled. Each time the lowest (or minimum), the mean, and the highest (or maximum) measured values were recorded (see Figure 2). The "average" of all of these values is given in Figure 4. There was a tendency for the P-wave amplitudes to decline during follow-up. For example,

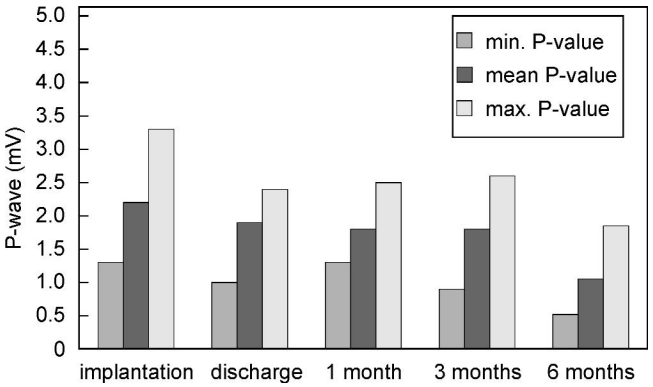

Figure 4. All measured P-wave amplitudes are represented in this figure. The minimum values are in the first row, the "mean" values in the middle row, and the maximum values in the last row. From left to right, the values shown are at implantation, discharge, 1 month, 3 months, and 6 months. All three values (minimum, "mean" and maximum) show a decrease during follow-up.

	Implantation		Discharge		1 month		3 months		6 months	
	n = 18		n = 16		n = 19		n = 17		n = 10	
	mean ± sd	range	mean ± sd	range	mean ± sd	range	mean ± sd	range	mean ± sd	range
Min.	1.3 ± 1.5	0.2 - 5.2	1.0 ± 1.3	0.1 - 4.8	1.3 ± 1.7	0.1 - 6.2	0.9 ± 1.1	0.1 - 4.0	0.51 ± 1.0	0.1 - 3.1
Mean	2.2 ± 1.6	0.5 - 6	1.9 ± 1.5	0.1 - 5.8	1.8 ± 1.8	0.1 - 6.7	1.8 ± 2.1	0.1 - 7.2	1.1 ± 1.5	0.2 - 3.4
Max.	3.3 ± 2.7	0.8 - 10	2.4 ± 1.6	0.2 - 6.3	2.5 ± 2.2	0.1 - 7.4	2.6 ± 2.5	0.1 - 8.7	1.9 ± 1.5	0.2 - 4.4

Table 4. Highest and lowest P-wave recordings (mV).

the "mean " P-value at implantation was 2.2 ± 1.6 mV; it declined to 1.8 ± 2.1 mV at 3 months. To foresee the problems with atrial undersensing, not only the "mean" but also the lowest and highest P-wave values were recorded (see Table 4). Furthermore, the range was very large over the measuring period of 12 seconds. P-wave values within 12 seconds varied between 0.1 and 2.1 mV or between 2.4 and 8.7 mV in individual patients at 3 months, or between 0.2 and 10 mV at implantation with an average value of 3.0 mV. The lowest value determined the functioning of the atrial tracking. The lowest or minimum P-wave amplitude measured was 0.1 mV, but it did not occur frequently. In Figure 5, an overview is given of the lowest = minimum P-wave amplitudes.

Despite low P-wave values of 0.1 mV, undersensing was noticed in two patients during follow-up. In one patient, temporary undersensing was noted at 1 month, and in another patient, the undersensing started at 6 months and remained for the rest of the follow-up period. In this patient, the average P-wave value at implantation was 4 mV (range 0.1 to 5.3 mV), and at discharge it was 4.1 mV. At 3 months, a marked decline in P-wave amplitude was seen with an average of 0.1 mV (range 0.1 to 1 mV, but no undersensing occurred during the test). The pacemaker was already set at the highest sensitivity. In the other 18 patients, atrial sensing was good.

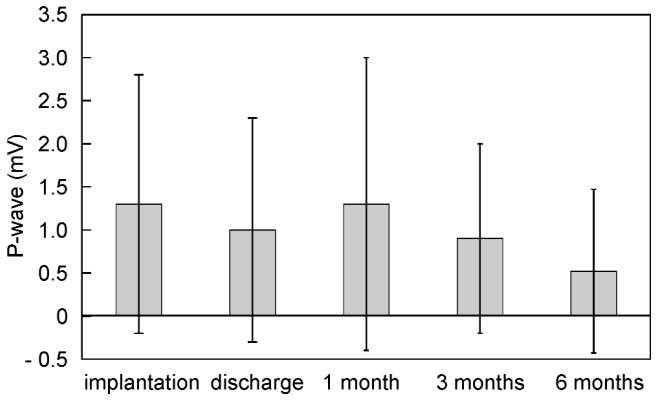

Figure 5. The "minimum" values of the P-wave amplitude are represented in a logarithmic scale. The lowest measured value is 0.1 mV. The highest "minimum" value is (for example) at implantation 5.2 mV. The Actros SLR will sense this "minimum" atrial signal without sensing remote activity of the ventricle.

Discussion

The principle of the floating single pass lead is based on a ventricular lead, which is safely anchored in the ventricle for pacing and sensing, and an atrial dipole on the lead passing through the right atrium which is capable of sensing the atrial activity without interference of the ventricle. It was stated that direct contact with the atrial wall was unnecessary. However, optimal tuning of the atrial electrode surface, inter-electrode distances, electrode sensing impedances, and frequency response of the atrial sensing amplifier were investigated and implemented [11]. Bipolar atrial sensing was found to be superior to uni-or combi-polar atrial sensing. The benefits of bipolar sensing were also stressed in other reports [5]. In absolute values, the "average" P-wave amplitude was not significantly lower than with dedicated atrial leads with the electrodes anchored in the atrial wall (12 channel). It was recognized that the floating electrode showed larger variations during breathing, postural change, exercise, or Valsalva maneuvers [12-14]. The main objections against these studies were that only the average of the measured values was given. In our study, the average value of the P-wave amplitude was 2.2 ± 1.6 mV. In our opinion, the range or the minimum values, which are not given in most other reports, gives a better insight into the variations of the atrial signal derived

from a floating electrode. An average of 2.2 ± 1.6 mV seems to be a good result; however, the range varies between 0.5 and 6.0 mV and the lowest values found during the check-up were as low as 0.2 mV.

Overall sensing characteristics were good. Loss of atrial tracking has been reported in other reports, varying between 6 % (inappropriate sensing) to 11 % (loss of AV-synchrony) [6,9]. Several factors may play a role in the low P-wave amplitude and the variations in these amplitudes. A larger right atrium is associated in a negative way with a poorer atrial signal: dilatation enlarges the distance from the atrial dipole to the atrial wall. Furthermore, atrial sensitivity should be adjusted to the atrial signal; the programmed sensing margin should be twice the measured sensing threshold [14]. It is therefore advisable to implant a pacemaker with high atrial sensitivity settings (the Actros SLR can be set to 0.1 mV). Another concern is that the pacing system analyzer can show larger, more optimistic results of the P-wave amplitude than the pacemaker telemetry [14]. In our series, a small, insignificant decrease is present between implantation versus discharge (normally on day 2 or 3 after the implantation).

In general, low P-wave amplitudes should be avoided during implantation because of the small decline of the average values during follow-up, and the variations of the atrial signal. In this series, only one patient had a poor atrial signal and showed some undersensing. Therefore, a P-wave of at least > 0.5 mV is strongly recommended [11]. However, in this study, one patient had an excellent implantation of the floating lead with an atrial signal of about 4 mV, but later it dropped markedly to 0.1 mV. We believe that lead dislocation was the cause. In no other patient had such dramatic changes been noticed.

One of the disadvantages is the fixed distance from the atrial dipole to the ventricular tip. Once the lead is introduced into the vein, it is spoiled if the optimum distance has not been selected. A very simple, but tricky method has been proposed by Nowak et al. [15]. Another useful method is echocardiographic measurements of the right atrial volumes and the right ventricular end diastolic volume, in order to optimize atrial sensing [16]. Positioning of the atrial dipole should be in the middle, or just below that of the right atrium in the vicinity of the free wall.

The trade-off for the single pass lead and VDDR pacemaker is the advantage of a relatively "simple" implantation versus the variations in atrial signal. The impossibility of pacing the atrium with a standard VDDR pacemaker has to be taken into account during patient selection; no patients with sick sinus node disease or chronotropic incompetence should receive a VDDR pacemaker. In this series, it has been shown that the SOLOX single pass lead is easy to handle and can generally be implanted quickly. Implantation time and positioning times are slightly better compared to one other report [4].

Conclusion

The SOLOX single pass lead for VDD pacing is easy to implant within a reasonable time, which is comparable to that of a ventricular lead. Atrial sensing values have to be measured. The levels of the initial atrial signal should be more than 0.5 mV, and preferably more than 0.8 mV, because variations and a small decrease of the average value may occur over time. Even with the well functioning ventricular part of the lead, it can be stated that good atrial signals are obtained with the SOLOX single pass lead. This occurs even when the worst data or minimum values are considered.

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