Single-Lead DDD System: A Comparative Evaluation of Unipolar, Bipolar and Overlapping Biphasic Stimulation

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Summary

Single-lead DDD pacing using unipolar or bipolar stimulation has been limited by high atrial thresholds. Overlapping biphasic (OLBI) waveform stimulation via atrial floating ring electrodes may preferentially enhance atrial stimulation and avoid diaphragmatic pacing. Single-lead DDD pacing using the OLBI pacing configuration was studied in 12 patienta (6 male, 6 female, mean age 74±7 years) with complete heart block. At implantation, atrial rings (area 27 mm², separation 10 mm) were positioned at radiological defined high, mid and low right atrium (RA). The P-wave amplitude, atrial and diaphragmatic pacing thresholds were determined at each position using unipolar, bipolar and OLBI stimulation configurations in randomized order.

Although statistically insignificant, the P-wave amplitude tended to be lower in the low RA position. Independent of the stimulation modes, minimum atrial pacing threshold occured in the mid RA. In the mid RA position , the atrial pacing threshold was significantly lower with the OLBI mode compared to either unipolar or bipolar mode (3,9±2,2V vs. 6,7±3,5V vs. 6,9±3,5V, p < 0,05). Althrough the diaphragmatic thresholds were similar, OLBI pacing modes in mid RA and final location sigificantly improved the safety margin for preventing diaphragmatic pacing compared to unipolar mode. By the time of pre-discharge testing, one patient developed atrial fibrillation, the remaining 11 patients had satisfactory atrial capture and stable atrial pacing threshold (day 0: 2,6±1,1V vs. day 2: 3,2±1,3V, p = ns). However, diaphragmatic pacing occured in 4/11 (36%) of patients especially during upright postures (sitting and standing).

Preliminary clinical results suggest that OLBI pacing via atrial floating ring electrodes can reduce atrial pacing treshold compared to unipolar and bipolar configurations. To optimize atrial pacing and sensing, the bipolar electrodes should be located at the mid RA position first, althrough the right RA may be alternative. Despite significant improvement of safety marginfor diaphragmatic pacing with OLBI pacing mode, diaphragmatic stimulation remains a clinical problem.

Key Words

Single-lead DDD stimulation, overlapping biphasic pulses, atrial stimulation, atrial threshold

Introduction

The successful application of sngle-lead VDD pacemaker systems to provide atrioventricular (AV) synchronous pacing [1-3] have prompted the development of a single-lead DDD pacemaker. Atrial sensing is accomplished with the use of either diagonally arranged bipole or closely spaced ring electrodes, with the use of a differential atrial amplifier and high atrial sensitivity [4]. However, single-lead dual chamber pacing using conventional pacing configurations (unipolar and bipolar) are limited by high atrial pacing threshold and has the potential disadvantage of diaphragmatic capture due to phrenic and nerve stimulation [5]. Preliminary studies have shown that a novel pacing stimulation waveform: overlapping biphasic (OLBI) stimulation using atrial floating ring electrode can dramatically reduce atrial pacing thresholds compared to either unipolar or bipolar stimulation and reduce the incidence of diaphragmatic pacing [6]. Thus the OLBI pacing configuration may be useful for single-lead DDD pacing, although the optimal position for atrial pacing and the relationship between atrial pacing and P-wave amplitude are unknown. The aims of this study were to evaluate:

- the acute (at implantation) strial and diaphragmatic pacing threshold using OLBI stimulation via floating ring atrial electrodes compared to unipolar and bipolar stimulation,
- the effect of right atrial electrode location on pacing and sensing threshold,
- the relationship between sensing and pacing threshold with floating atrial electrodes.

Methods

Study Population

Twelve consecutive patients (6 male, 6 female, mean age 74±7 years) with complete AV block who fulfilled the following criteria for implantation of a single-lead VDD pacemaker were included:

- normal sinus rhythm
- normale sinus node function when assessed using a 12-lead ECG and scutely monitoring electrocardiograms,
- no previous documented history of atrial fibrillation or sick sinus syndrome.

Single pass VDD lead

The single pass VDD lead (model SL 60/UP, BIOTRONIK GmbH, Berlin, Germany) is a unipolar, passive fixation lead. The lead has three different configurations which vary the distance between the venticular pacing electrode and the atrial ring electrodes. The atrial ring electrodes have a fractal surface structure with a geometrical area of 2 cm², are seperated by 10 mm, and provide bipolar atrial sensing and pacing functionality. The total lead length is 60 cm and the appropriate lead configuration to be implanted was selected according to heart size estimated from the chest roentgenogram, such that the ventricular lead tip and the atrial electrodes can be positioned in the right ventricular apex and in the mid right atrium (RA), respectively.

Study Protocol

The leads were inserted via either cephalic venous cutdown or subclavian venous puncture. The ventricular electrode was first positioned in the right ventricular apex to achieve pacing threshold lower then 1V (at a pulse width of 0,5ms) and endocavity signal higher than 5mV. The atrial electrodes were then positioned at three different atrial locations: high, mid or low RA as guided by the fluoroscopy. At each location the P-wave amplitude, atrial and diaphragmatic pacing thresholds were determined as described below.

After the initial assessment, the atrial electrodes were repositioned to an optimal location, defined as a position where:

- the atrial electrodes were free-floating in the atrial cavity,
- the P-wave signal amplitude was > 0,5mV.

A VDD pacemaker (Model DROMOS SL M7/M8, BIOTRONIK GmbH, Berlin, Germany) was then implanted in the pectoral region in all patients. The pacemaker is a VDD device, but can be programmed temporarily to DDD mode to provide atrial pacing via floating ring electrodes using the OLBI mode.

Atrial Sensing

At each RA location, the unipolar and bipolar atrial sensing were measured. The P-wave amplitudes were determined by using a pacing system analyzer's (ERA 300, BIOTRONIK GmbH, Berlin, Germany) measurement function, which measures a filtered (15ms-sin² filter) P-wave amplitude. In a sequence of 13 heart cycles, the maximum and minimum P-wave amplitude were measured with the patients breathing quietly.

Atrial and Diaphragmatic Pacing Threshold

The atrial and diaphragmatic pacing threshold were determined at each of the three RA locations for the following pacing configurations:

- unipolar stimulation with the distal electrode as anode (pulse width 0,5ms)
- bipolar stimulation using the proximal electrode as cathode and the diastal electrode as anode (pulse width 0,5ms) and
- OLBI stimulation mode 7: the first positive monophasic rectangular pulse [+] is applied to the distal electrode and the second negative monophasic rectangular pulse [-] is applied to the proximal electrode (see Figure 1).
- An alternative OLBI stimulation mode 8: used a negative [-] first pulse (distal electrode) and a positive [+] second pulse (proximal electrode), as shown in Figure 1. The pulse width used in each case are 0,5ms with no delay between the first and the second pulses.

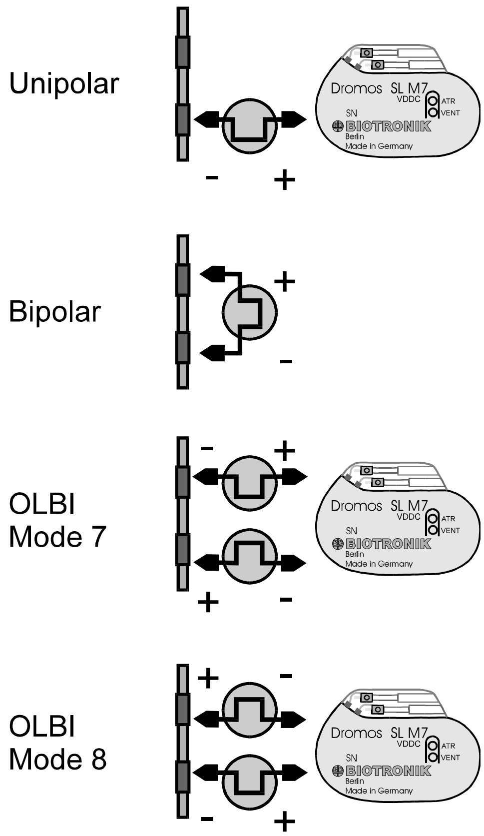

Figure 1. *Atrial pacing waveforms used in this study. The 2 rings represent the proximal (top) and the distal (bottom) bipolar atrial electrodes.*

Starting at the highest output of 10V, the pacing thresholds were measured using a step-down protocol with a step of 0,2V. Diaphragmatic stimulation was continuously monitored by detecting movement at the upper epigastrium. Diaphragmatic and pacing thresholds were defined as the output when the first loss of capture of the diaphragm (if any) or atrium was detected, respectively.

Temporary DDD Pacing at Pre-discharge Testing

Before discharge, teh temporary DDD mode using OLBI pulse stimulation for atrial pacingwas activated in all Patients and the pacing and diaphragmatic threshold measured with the patients supine. The atrial pacing output using OLBI mode was then programmed at 2 times the pacing threshold or to a maximum of 4,8V (at pulse width of 0,5ms). The efficacy of atrial and diaphragmatic pacing was also determined in the sitting and standing postures.

Statistical analysis

All values are expressed as mean ± SD. Comparisation between variables was performed by two-tailed unpaired Student's *t*-test. Bonferroni correction was supplied for multiple comparisations. A P value <0,5 was considered significant.

Results

Single pass VDD lead

VDD leads with 11, 13 and 15cm separation were chosen in 8, 3 and 1 patient(s) respectively. All patients had satisfactory ventricular sensing (mean R-wave amplitude: 11,7±4,1mV, range: 7,5-18,6mV) and pacing (pacing threshold: 0,6±0,2V at 0,5ms pulse width, range: 0,3-0,9V) parameters. There was no lead dislogment nor other implantation related complications.

Atrial Sensing

In each of the RA locations, the bipolar sensing P-wave amplitude were higher then unipolar. Although statistically insignificant, both the average maximum and minimum P-wave amplitudes tended to be lowest in the low RA position and the average minimum bipolar sensing P-wave amplitude tended to be higher in mid RA (see Figure 2). The optimal location for P-wave amplitudes were variable between patients. The final atrial electrode positioning was high RA in 3 patients, mid RA 8 patients and low RA 1 patient. The average minimum bipolar sensing P-wave amplitude was 1,1–0,6mV in the final position.

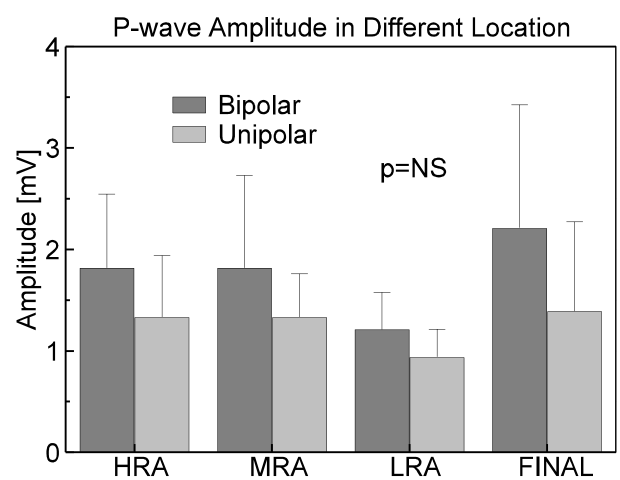

Figure 2. *Mean P-wave amplitudes at different right atrial locations. Abbreviations: HRA = high right atrium, MRA = mid right atrium, LRA = low right atrium.*

Atrial and Diaphragmatic Pacing Treshold

There was no significant difference in atrial and diaphragmatic pacing threshold between OLBI modes

7 and 8. For further statistical analysis the results of mode 7 were used for comparison.

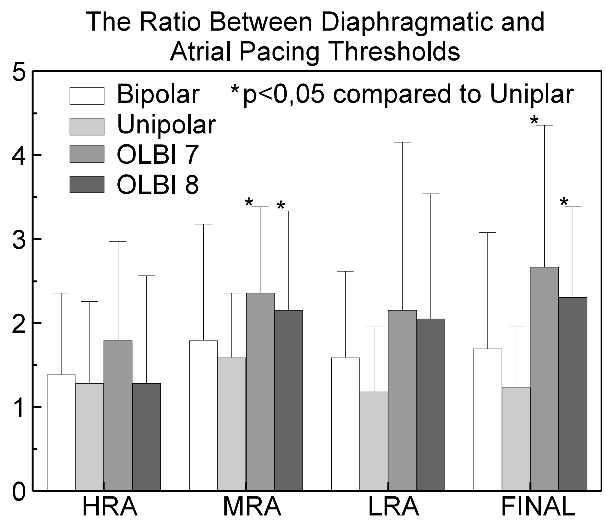

Figure 3. *Atrial and diaphragmatic pacing thresholds at different right atrial locations and at final right atrial location. Abbreviations: HRA = high right atrium, MRA = mid right atrium, LRA = low right atrium, OLBI = overlapping biphasic.*

For both unipolar and bipolar pacing stimulation, there was no difference in atrial pacing threshold in all three RA locations. Independent of the pacing location, OLBI pacing modes had consistently lower atrial pacing threshold compared to both bipolar pacing modes (see Figure 3).

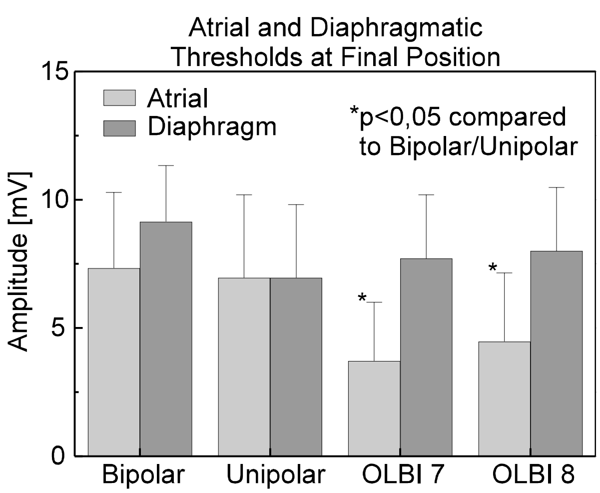

Figure 4. *The ration between atrial and diaphragmatic pacing thresholds using different pacing modes in different right atrial location. Abbreviations: OLBI = overlapping biphasic.*

The lowest OLBI stimulation threshold was achieved in the mid RA location. In the final atrial electrode location, OLBI pacing mode also had significantly lower atrial pacing threshold compared with bipolar and unipolar modes (see Figure 3). Diaphragmatic pacing threshold is independent of RA locations and the pacing modes of the stimulation electrodes.

OLBI pacing modes had a higher „safety“ margin between diaphragmatic and atrial pacing thresholds compared with either bipolar or unipolar in atrial locations (see Figure 4).

In mid RA and final atrial location, this margin was significantly greater during OLBI pacing modes compared with unipolar mode but no significant difference was present between OLBI and bipolar modes. There was no significant correlation between the minimum P-wave amplitude and the corresponding atrial pacing threshold (see Table 1).

	P min		P max		P mean	
	r	P value	r	P value	r	P value
HRA						
Bi	0,39	0,34	0,73	0,05	0,64	0,09
Ui	0,25	0,56	0,39	0,33	0,36	0,37
OLBI	0,55	0,16	0,66	0,07	0,65	0,08
MRA						
Bi	-0,03	0,94	0,04	0,92	0,02	0,97
Ui	-0,35	0,40	-0,26	0,53	-0,30	0,47
OLBI	0,33	0,43	0,56	0,15	0,49	0,22
LRA						
Bi	0,55	0,16	0,50	0,21	0,54	0,17
Ui	0,36	0,37	0,13	0,77	0,23	0,58
OLBI	0,59	0,13	0,40	0,33	0,50	0,21

P min = minimum P-wave amplitudes; P max = maximum P-wave amplitudes; P mean = mean P-wave amplitudes; HRA = high right atrium; MRA = mid right atrium; LRA = low right atrium; Bi = bipolar; Ui = unipolar; OLBI = overlapping biphasic; r = correlation coefficient.

Table 1. *Correlation between bipolar P-wave amplitudes with pacing thresholds at different right atrial locations using different pacing modes.*

Temporary DDD pacing at Pre-discharge Testing

Except for 1 patient who developed atrial fibrillation immediately after implantation, all other patients had successful atrial capture in the DDD mode. There was no acute change in atrial pacing threshold using OLBI mode (day 0: 2,6±1,1V vs. day 2: 3,2±1,3V, p = ns). However, 4 patients experienced diaphragmatic pacing at a mean pacing output of 4,6±0,4V (sitting: 2, standing: 4).

Discussion

Single-lead VDD pacing systems offer a reasonable to DDD pacing in patients with pur AV block with no evidence of sinus node disease. Implantation and follow-up procedures are simplified, and cost is usually reduced by more then the cost of an additional atrial lead. However, as atrial pacing is not possible, loss of AV synchrony and rate response may occur for unrecognized or progressive sinus node disease. The development of a single-lead DDD system may overcome this limitation.

To date, single-lead DDD pacing has been possible, but is limited by unacceptably high atrial pacing threshold using conventional bipolar or unipolar modes of stimulation [5]. Even if energy cost is not considered, atrial pacing using high energy stimulation via a floating atrial electrode may lead to phrenic nerve stimulation and diaphragmatic capture. Recently, a novel pacing method using two unipolar rectangular pacing pulses of opposite polaryty (overlapping biphasic waveform) delivered via two atrial ring electrodes has been shown to reduce atrial pacing threshold by increasing the current desity of the stimulation pulse at the atrial endocardium. Furthermore, by concentrating the field potentials around the atrial electrodes the OLBI pacing configuration reduces the incidence of diaphragmatic pacing [6].

In the present study, OLBI pacing modes consistently lowered the atrial pacing threshold compared with bipolar and unipolar pacing modes for all RA locations. However, unlike a previous report in animals [6], there was no difference in the diaphragmatic pacing threshold between stimulation modes. Thus the efficacy of the OLBI pacing waveform in the human right atrium is mediated by a larger safety margin between diaphragmatic and atrial pacing. There was no significant difference in pacing thresholds when using either the anode or cathode for positive stimulation pulse in OLBI stimulation (mode 7 vs. mode 8).

It has been previously documented that the mid RA location is usually associated with the best P-wave sensing [4], but significant inter-patient variability of P-wave sensing occurred at different RA locations. On the other hand, the optimum RA location for atrial pacing and the relationship between atrial sensing and pacing threshold via floating strial electrodes are unknown. In this study, we confirmed that the mid RA location was associated with the largest average minimum bipolar sensing P-wave amplitude. Independent of the modes of stimulation, the mid RA location had the lowest mean atrial pacing threshold. Furthermore, OLBI pacing modes in mid RA location had significantly lower atrial pacing threshold compared with either unipolar or bipolar pacing mode. Thus, mid RA location was found to be the best atrial electrode position with the highest sensing P-wave amplitude for atrial sensing and the lowest threshold for atrial pacing. Consistent with our general impression that the good P-wave sensing does not predict a better atrial pacing threshold, no significant correlation between the P-wave amplitude and atrial pacing threshold could be found. This may be due to the wide variation in the pacing threshold and the sensing P-wave amplitude associated with the floating atrial electrode. Despide the significantly reduction in atrial pacing threshold and improvement in the safety margin of OLBI waveform in preventing diaphragmatic pacing, a significan proportion of patients (4/11 patients, 36%) still experience diaphragmatic pacing at a atrial output of 2 times threshold (or maximum of 4,8V), especially in upright posture.

Conclusion

Our preliminary clinical results suggest that OLBI pacing via floating ring electrodescan reduce atrial pacing threshold, the „safety margin“ for atrial copture increased compared to other stimulation modes. Mid RA position was found to be the best atrial electrode position for pacing and sensing, and should be the initial position for implantation. Since the RA location has a greater impact on atrial pacing then sensing, in a single-lead DDD system the pacing configuration should preferably be optimized during positioning of atrial electrode. Despide the improvement in atrial pacing threshold and safety margin for preventing diaphragmatic pacing by using OLBI pacing mode, diaphragmatic stimulation remains a significant clinical problem, especially when the patients have ambulated after pacemaker implantation.

References

[1] Ansani L, percoco GF, Guardigli G, Toselli T, Antonioli GE. Long-term reliability of single-lead atrial synchronous pacing systems using closely

spaced atrail dipoles. Five-year experience. PACE 1994; 17: 1865-1869.

[2] Lau CP, Tai YT, Li JPS, et al. Clinical Experience with the first single-lead VDDR pacemaker. PACE 1993; 15: 1094-1100.

[3] Lau CP, Tai YT, Leung SK, et al. Long term stability of P-wave sensing in single-lead VDDR pacing: clinical versus subclinical atrial undersensing. PACE 1994; 17:1849-1853.

[4] Lau CP, Tai YT, Lee ISF. Comparative evaluation of acute and long term clinical performance of two single-lead atrial synchronous ventricular (VDD) pacemaker: diagonally-arranged bipolar versus closely-spaced bipolar ring electrodes. PACE (in press).

[5] Hirschberg J, Ekwall C, Srandberg H, Carlsten J, Bowald S. A new dual chamber single-lead system. PACE 1994; 17:1870-1872.

[6] Hartung WM, Hidden-Lucet F, McTeague K, Honeycutt C, Langberg JJ. Overlapping biphasic stimulation: A novel pacing mode with low capture thresholds. (Abstract) Circulation 1994; 90: 69.