Optimal Side of Implant for Single-Lead VDD Pacing: Right-Sided Versus Left-Sided Implantation

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HAGHJOO, M., ET AL.: Optimal Side of Implant for Single-Lead VDD Pacing: Right-Sided Versus Left-Sided Implantation. ***Background:*** *Atrial undersensing occurs in a considerable number of patients with single-lead VDD pacing. This study tried to determine the role of implant side in maintenance of the VDD mode in patients with isolated atrioventricular (AV) block.*

Methods: *Eighty-two patients with isolated AV block (46 females; mean age, 58 ± 17 years) received a single-lead VDD pacemaker (Medtronic Kappa, n = 70 and St. Jude Medical Affinity, n = 12). The patients were randomly assigned to one of two implantation groups (group I: right-sided VDD and group II: left-sided VDD). In each group, the P-wave amplitudes were determined at implantation, predischarge, 2-month, and 6-month follow-up. At each follow-up visit, stored event histograms of pacemaker were also retrieved. The atrial sensing measurements were compared between two groups.*

Results: *Implantation was easier from right side (1.7 ± 1.0 vs 2.8 ± 1.7 attempts, P = 0.001). Implant P-wave was higher in group I compared to group II (4.2 ± 1.7 vs 2.7 ± 1.0 mV, P < 0.0001). During follow-up, higher P-wave amplitudes were obtained in group I both at predischarge (2.6 ± 1.3 vs 1.4 ± 1.1 mV, P < 0.0001), 2-month (2.8 ± 1.8 vs 1.3 ± 1.0 mV, P < 0.0001), and 6-month (2.9 ± 1.7 vs 1.3 ± 0.9 mV, P < 0.0001) evaluations but remained stable throughout the 6 months in both groups. After implantation, VDD function was better maintained in group I than group II (100% vs 90%, P = 0.026). Incidence of atrial undersensing was lower in group I than group II (P = 0.026) in last follow-up visit.*

Conclusions: *Implant side has a significant influence on atrial sensing performance in single-lead VDD pacing. Thus, right-side implantation should be the preferred approach for the implantation of VDD single-lead systems. (PACE 2005; 28:384–390)*

single-lead VDD pacing, atrial sensing, implant side, atrioventricular block

Introduction

Since its introduction in the early 1970s,[1] single-lead VDD pacing has become a reliable alternative to DDD systems for patients with various degrees of atrioventricular (AV) block and normal sinus node function. It offers long-term reliable sensing and makes the implanter's work both simpler and quicker.[2] Although every attempt has been made for improving atrial sensing function of single-lead VDD pacing by selecting the right candidate patient,[3] positioning of atrial dipole in proper location,[4] using electrodes with different designs,[5] activating autosensing algorithm,[6] and programming the most sensitive setting for atrial sensing,[7] intermittent atrial undersensing remains a problem in this pacing system.[8] Consequently, the identification of methods contributing to a better performance of single-lead VDD pacemaker would be desirable. We, therefore, investigated the role of implant side, which hitherto has not been systematically investigated, in the maintenance of AV synchrony in single-lead VDD pacing system.

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Patients and Methods

Patient's Characteristics

Between August 2002 and September 2003, 82 consecutive patients with symptomatic or high degree AV block were enrolled in this study. The patients were randomly assigned to receive either right-sided or left-sided VDD implantation (group I: right-side implantation and group II: left-side implantation). The study was approved by local ethics committee, and written informed consents were obtained from all the patients. Mean age at implantation was 58 ± 17 years (range 12–82 years), and 56% of the patients were females. Pacemaker indication was complete AV block in 67.0%, second-degree AV block in 28.0%, and trifascicular block in 5%. At the time of pacemaker implantation, structural heart disease was present in 57.3% of the patients. Coronary artery disease or a history of coronary artery bypass grafting was present in 22.0% of the patients. Congenital AV block was present in 11.0% of the patients, 2.3% of the patients received pacemaker as a complication of cardiac surgery, and 22.0% of the

patients suffered from systemic arterial hypertension. Idiopathic (senescent) AV block was found in 42.7% of the patients. Inclusion criteria of this study were: (1) second- or third-degree AV block and (2) normal sinus node function as evidenced by sinus rate ≥90 bpm at rest in patients with stable AV block and sinus rate ≥70 bpm in the cases of trifascicular block.[9–11] Patients were excluded if there was evidence of (1) sinus node dysfunction, (2) a history of paroxysmal supraventricular tachyarrhythmia,[11,12] and (3) cardiomegaly especially right heart dilation (right atrium dimension >38 mm).[11,12]

Pacing System

Two different VDD pacing systems were implanted for the patients: Medtronic Kappa VDD 701 (Minneapolis, MN, USA) with Capsure® 5038 lead (n = 70) and St. Jude Medical Affinity VDR 5430 (St. Paul, MN, USA) with AV PLUS® DX 1368 lead (n = 12). These devices were capable of reporting the percentage of paced and sensed beats in the atrium and ventricle. All the pacemakers were programmed for bipolar sensing with atrial sensitivities between 0.10 and 0.18 mV.

The Medtronic Capsure® 5038 and St. Jude AV PLUS® DX 1368 are bifurcated, bipolar, coaxial, silicone-insulated, tined, and steroid-eluting leads equipped with floating atrial ring dipole. The Medtronic 5038 lead is available in three different models according to the distance between the atrial ring dipole and the distal ventricular electrode (A-V spacing): 11.5, 13.5, and 15.5. In these leads, the ventricular tip and ring electrode consisted of platinum alloy with a surface area of 5.8 mm^2 and 36 mm^2, respectively. Two rings of platinum alloy with a surface area of 12.5 mm^2 each and a distance of 8.6 mm were used for atrial sensing. The 58 cm lead length with 13.5 cm A-V spacing was the only one used in our study from Medtronic Capsure® 5038 leads. The St. Jude AV PLUS® DX 1368 lead is available in lengths of 52, 58, and 65 cm. In these leads, the ventricular tip and ring electrode consisted of platinum-iridium with a surface area of 5.0 mm^2 and 32 mm^2, respectively. Two rings of platinum-iridium with interelectrode distance of 11.9 mm were used for atrial sensing. Lead length of 58 cm with A-V spacing 13 cm was used in our study from St. Jude AV PLUS® DX leads.

Implantation Technique

Devices were implanted in electrophysiology laboratory using standard implant techniques with local anesthetic. All the patients were in sinus rhythm at the time of implantation. Implanting physicians were all qualified electrophysiologists. The lead was inserted through the subclavian vein (right-side 50% and left-side 50%) using a 9 or 10 French peel-away sheath. The choice of implantation site was randomized. In this study, no cephalic vein approach was used because we generally prefer to employ subclavian vein as the venous access in our electrophysiology laboratory and we have also had difficulty in traversing relatively large diameter VDD leads through the cephalic vein in some of our prior patients. After the placement of VDD lead in right ventricular apex and obtaining adequate sensing and pacing thresholds, atrial sensing was assessed by atrial mapping: Firstly, the proximal part of the lead was moved backwards in the direction of the superior vena cava (SVC). Then, the atrial dipole was bowed to move distally in an inferior direction toward the middle part of the right atrium (avoiding from low right atrium because of report of higher incidence of atrial undersensing in several published studies).[4,7–9,13] Priority was placed on obtaining maximum mean atrial sensing amplitude during shallow and deep breathing. At optimal atrial dipole location, the stability of mean atrial sensing amplitude was checked using maneuvers such as deep inspiration and coughing. Atrial and ventricular sensing and pacing thresholds were determined using pacing system analyzer (PSA) 5311 (Medtronic Inc.). In all the instances, analyzer display informations were used to measure P-wave amplitude, R-wave amplitude, impedance, and stimulation threshold. The acceptable atrial signal amplitude measured via the atrial channel was ≥1.5 mV (or minimal P-wave ≥1.0 mV[11]), both in shallow and deep breathing. The acceptable values for ventricular sensing and pacing thresholds were ≥5.0 mV and ≤1.0 V, respectively. The atrial dipole repositioning was required if atrial signal amplitude was <1.5 mV. Finally, lead was secured using the sleeve immediately outside the puncture site and anchored to VDD pulse generator. All the cases were checked for atrial dipole displacement under fluoroscopy before pocket closure. All the pacemakers were programmed at a lower rate of 40 beats/min, sensed AV interval of 150 ms and upper tracking rate of 120–140 beats/min depending on the age and level of physical activity. Atrial sensitivity was set at highest sensitivity value (0.10–0.18 mV).[11] Isometric exercise of upper extremities was done to check for myopotential oversensing by atrial dipole.

Follow-Up

Atrial signal amplitude was measured during shallow and deep breathing in the supine position at predischarge (24 hour), 2 and 6 months after implantation. Medtronic 9790 and St. Jude 3510/3500 programmers were used to measure atrial signal amplitude, monitor P-wave

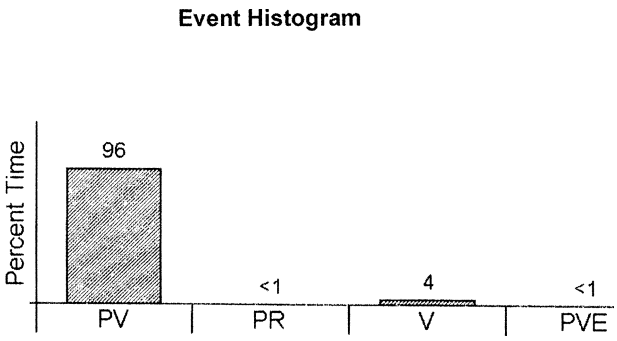

Figure 1. *An example of stored event histogram of VDD pacemaker. This histogram reports the percentage of AS-VS, AS-VP, VP, and PVE in all counted beats. This percentage can be used to calculate the percentage of atrioventricular synchrony.*

undersensing and retrieve stored event histogram (Fig. 1) in follow-up visits.

Definitions

Atrial undersensing was defined by the presence of one of the following criteria: (1) evidence of less than 95% AV synchrony in event histogram of pacemaker, (2) loss of detection of at least one P-wave during shallow and deep breathing in the supine position indicated by surface electrocardiogram (ECG) and telemetered marker annotations, and (3) P-wave amplitude $\leq$0.10–0.18 mV at each follow-up visit. *Significant atrial undersensing* was characterized by any symptomatic undersensing needing reprogramming to VVIR mode or upgrading to DDD mode. *Asymptomatic atrial undersensing* refers to any episodes of atrial undersensing needing no intervention due to low clinical relevance. Ventricular pacing with no preceding atrial sensed event (VP) was considered as improper function of the VDD system, while atrial sensing-ventricular sensing (AS-VS) and atrial sensing-ventricular pacing (AS-VP) indicated proper AV synchrony.

Statistical Analysis

Data are presented as mean ± SD and ranged when appropriate. Continuous variables were compared by Student's *t*-test. Comparison of categorical variables was done by χ^2-test. A P value < 0.05 was defined statistically significant. The software SPSS version 11.0 (SPSS Inc., Chicago, IL, USA) was used for statistical analysis.

Results

Eighty-two consecutive patients having various degrees of isolated AV block were entered in our study. Each studied group consisted of 41 patients, who received single-lead VDD pacing. The preimplant characteristics of all included patients are presented in Table I. A comparison of the two study groups showed no statistically significant difference in clinical characteristics and implanted devices (Table I).

Measurements at Implant

At implant, P-wave amplitude measured by PSA was 3.4 ± 1.6 mV (range, 1.5–8.6 mV). PSA P-wave amplitude was 2.7 ± 1.0 mV in group II compared to 4.2 ± 1.7 mV in group I (P < 0.0001). A P-wave amplitude $\geq$1.5 mV was achieved in all the patients. The minimum/mean/maximum values of atrial signals were summarized in Table II. The ventricular pacing threshold was 0.50 ± 0.32 mV at 0.5 ms in group I compared to 0.47 ± 0.34 mV at 0.5 ms in group II (P = 0.24). The ventricular impedance and R-wave amplitude were, respectively, 711 ± 133 Ω and 11.2 ± 3.0 mV (P = 0.42) in group I compared to 683 ± 122 Ω and 11.1 ± 3.3 mV (P = 0.50) in group II. The mean number of attempts for atrial dipole positioning from the right side was 1.7 ± 1.0 compared to 2.8 ± 1.7 in left side (P = 0.001). Finally, atrial dipole was placed in mid-right atrium in all the patients of both groups (100%).

Measurements at Predischarge

At predischarge, P-wave amplitude measured by programmer was 2.0 ± 1.3 mV (range, 0.18–5.6 mV). Programmer-determined P-wave amplitude was 1.4 ± 1.1 mV in group II versus 2.6 ± 1.3 mV in group I (P < 0.0001). In both groups, a 40% diminution was seen between values obtained at implant with a PSA and those determined by the programmer at predischarge. The percentage of AV synchrony was not significantly different between the two groups at this stage (99% in group I vs 98% in group II), although a trend was seen for better AV synchronization in group I (P = 0.07).

Measurements at 2 Months Postimplantation

Two months after implantation, sensed P-wave amplitude, determined by programmer, was 2.1 ± 1.6 mV (range, 0.10–7.0 mV). A statistically significant difference was seen in atrial signal amplitude between the two groups (group I: 2.8 ± 1.8 mV and group II: 1.3 ± 1.0 mV; P < 0.0001) at 2-month follow-up visit. Percentage of AV synchrony was 99% in group I compared to 94% in group II (P < 0.0001).

Measurements at 6 Months Postimplantation

Electrical measurements of 6 months postimplantation were similar to those of 2-month follow-up (2.1 ± 1.6 mV; range, 0.10–7.0 mV). P-wave amplitude was 2.9 ± 1.7 mV in group I compared to 1.3 ± 0.9 mV in group II (P < 0.0001). Difference

Table I.

Preimplant Patient Characteristics

Variable	Total	Group I*	Group II*	P value
Number of patients	82	41	41	
Male/female (no.)	36/46	17/24	19/22	0.60
Age (years, mean ± SD)	58 ± 17	57 ± 16	59 ± 18	0.59
Resting sinus rate (beats/min, mean ± SD)	97.6 ± 7.5	96.9 ± 5.4	99.6 ± 7.4	0.076
Ejection fraction (%, mean ± SD)	49.9 ± 6.0	50.5 ± 5.9	49.4 ± 6.2	0.408
Underlying heart disease (no.)				
Ischemic	18	10	8	0.51
Hypertensive	18	8	10	0.52
Congenital	9	4	5	0.49
Postoperative	2	1	1	0.53
Idiopathic	35	18	17	0.52
Pacemaker indication (%)				
Third-degree AVB†	67.0	57.5	77.5	0.125
Second-degree AVB	28.0	37.5	17.5	0.129
Trifascicular block	5	5	5	0.124
Pacing system model (no.)				
Medtronic Kappa 701	70	33	37	0.35
St. Jude Medical Affinity	12	8	4	0.34
Follow-up duration (months)	6	6	6	

*Group I: right-sided VDD; Group II: left-sided VDD.
†AVB = atrioventricular block.

between the percentages of AV synchrony of the two groups was statistically significant (group I, 99% vs group II, 93%; $P < 0.0001$).

Atrial Sensing Over Time

In each group, the mean values of the atrial signal measured at predischarge were statistically lower ($P < 0.0001$) than those determined under same conditions at implantation. No significant differences were found in mean atrial signal amplitude between predischarge and at 2-month follow-up ($P = 0.18$). The mean values of atrial signal amplitude were not different between 2 and 6 months after implantation ($P = 0.26$), although a trend was seen for the improvement of atrial sensing function in group I over time.

Table II.

Minimal/Mean/Maximum P-wave Amplitude Measured at the Implantation

	Group I	Group II	P value
Minimal P-wave amplitude (mV)	2.44 ± 1.0	1.72 ± 0.69	<0.0001
Maximum P-wave amplitude (mV)	5.12 ± 1.9	3.5 ± 1.34	<0.0001
Mean P-wave amplitude (mV)	4.2 ± 1.7	2.7 ± 1.0	<0.0001

Group I: right-sided implantation; Group II: left-sided implantation.

Maintenance of VDD Mode

Of the 82 patients studied, 6 (7%) were no longer in VDD mode at their last follow-up visit because of significant atrial undersensing despite programming of highest atrial sensitivity. These patients required reprogramming to VVIR mode. Upgrading was not considered beneficial in any patient. Intermittent asymptomatic atrial undersensing occurred in additional 2 patients. Two patients (1 patient in each group) with atrial undersensing had displacement of atrial dipole to SVC at 2-month follow-up visits. Remaining 6 patients belong to group II (without evidence of dipole displacement in any direction). In those patients without atrial dipole displacement, there was statistically significant difference in the maintenance rate of VDD mode between the two groups (90% in group II vs 100% in group I, $P = 0.026$). Fortunately, no patient required reprogramming because of the development of atrial tachyarrhythmias or sinus node dysfunction. The average percentage of AV synchrony in patients who

were in VDD mode was 98%, 96%, and 96% at predischarge, 2- and 6-month follow-up visits, respectively. There were statistically significant differences in the percentage of AV synchronization between the two groups at 2- and 6-month follow-up ($P < 0.0001$).

Pacing Outcome

Intermittent atrial undersensing occurred in 3 (3.6%) VDD patients at predischarge in spite of the programming of the device to the highest atrial sensitivity. Chest x-ray revealed no evidence of atrial dipole displacement in any directions (from the position at implantation) in these patients. Reprogramming was not done at this time because of low clinical relevance. No other early complications occurred in our patients. At the first 2 months, 8 (9.7%) patients showed intermittent atrial undersensing. Of these patients, 6 (7%) patients needed reprogramming to VVIR mode because of inadequate atrial sensing and symptomatic sinus bradycardia. Two of six patients with atrial undersensing (1 patient in each implantation group) showed displacement of atrial dipole to SVC. Remaining 4 patients (all from group II) had no evidence of dipole displacement. No other lead-related or implant-related complications were observed at this time. At the last follow-up visit, no new evidence of atrial undersensing was seen in any patients. We also had no new device-related complications. During 6-month follow-up, no evidence of sinus node dysfunction or atrial tachyarrhythmia was found in our study population. There were statistically significant differences in the incidence of atrial undersensing at 2- and 6-month follow-up visits between the two-implantation groups ($P = 0.026$).

Discussion

As its introduction, VDD pacing has been used increasingly in patients with AV block and normal sinus node function. The reliability of this pacing system has been demonstrated in several studies.[9,11,12,14,15] However, due to a great variation of the atrial potential received by free-floating electrodes[16] and instability of atrial dipole during changes in posture,[17,18] intermittent atrial undersensing remains a potential problem in single-lead VDD pacing. Many studies have tried to define the predictors of long-term failure of VDD pacing and to test the effects of new sensing algorithm and dipole design on the incidence of atrial undersensing.[5,6] Recently, Choi et al.[17] suggested an interesting technique using chest x-ray for preimplant prediction of posture dependent changes in atrial sensing performance of VDD pacemaker. These efforts have somewhat been effective in the maintenance of proper VDD function, but atrial undersensing has persisted. Until now, no systematic study has focused on the role of implantation side on atrial sensing function of single-lead VDD pacing. We conducted a prospective study to address this issue.

Implantation Side and Procedural Difficulties

Even though lead tip positioning in RV apex is usually easier from the left side than that the right side, in our study right-sided VDD implantation was accomplished easier than left-sided implantation regarding to the number of attempts for atrial dipole positioning. Lesser attempts at dipole positioning could lead to the shortening of implant time in group I, albeit implant time was not calculated in our patients. In both groups, similarly acceptable electrical parameters were achieved in the right ventricle at implantation.

Implantation Side and Atrial Sensing Function

There was a significant decrease in atrial signal amplitude, measured by PSA and telemetry on the next day after implantation. No difference was found among the serial measurements of atrial signal after implantation and during follow-up visits. These results are in keeping with the findings of other studies.[12,15] The reason for the observed drop in atrial signal amplitude between PSA and telemetry measurements may be related to equipment differences, including not only the amplifiers, but also the difference in the sampling methods and blanking capabilities of the two different instruments.[2] Although the above-mentioned pattern of serial atrial signal changes was seen in both studied groups, atrial signal measurements were always in favor of group I, both at implantation and follow-up visits. The average percentage of AV synchrony in patients who were in VDD mode was 96% at the last follow-up visit. Previous studies have reported both somewhat lower and higher AV synchrony from 93.7%[3] to 99.7%.[19] There was a statistically significant difference in the percentage of AV synchronization between the two groups at the last follow-up ($P < 0.0001$). More importantly, 93% of the pacemakers functioned satisfactorily in the VDD mode, with only 7% of the patients dropping out for significant atrial undersensing. The maintenance rate of VDD mode was similar to that of the findings of European multicenter study by Crick et al.[20] There was a statistically significant difference in the maintenance rate of VDD between the two groups ($P = 0.026$). Our hypothesis for a better outcome of VDD pacing in group I is the presence of an extra-bend of lead in SVC dragging the atrial dipole to close

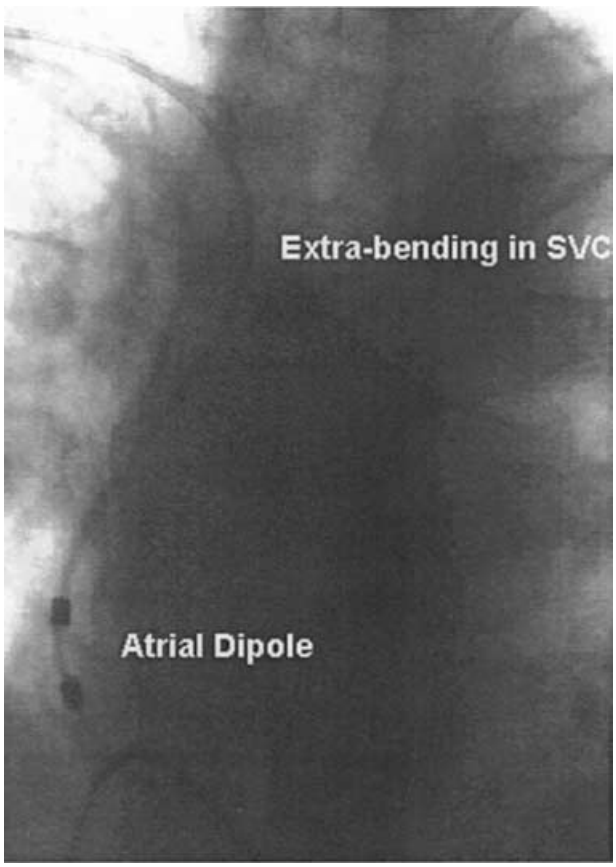

Figure 2. *Postoperative fluoroscopy of a patient with right-sided VDD pacemaker. Note the extra-bending of lead in SVC drags the atrial dipole to close proximity of atrial wall.*

proximity of the right atrial (RA) wall (Fig. 2). Close proximity to RA lateral wall leads to better atrial sensing function because the distance between the dipole and the atrial wall is the key factor for stable sensitivity.[12] Although it might be possible to design such an extra-bend of lead from the left, this maneuver is simpler and easier from the right. We also believe that formation of such an extra-bend against the SVC wall from the right side leads to stabilization of atrial dipole in mid-part of RA (an optimal location for atrial dipole) but trying to make a similar bend from the left could displace the atrial dipole to low RA (a location with acceptable acute atrial signal amplitude but considerable atrial undersensing[4,7–9,13]).

Implantation Side and Incidence of Atrial Undersensing

Intermittent atrial undersensing was seen in 3.6% of our patients in predischarge evaluation despite programming of highest atrial sensitivity. This may be explained by using mean P-wave amplitude instead of minimal P-wave amplitude (a better predictor of undersensing) in our analyses. All of the patients were completely asymptomatic at this stage, thus needing no intervention. Two months after implantation, incidence of atrial undersensing increased to 9.7%. Six patients became symptomatic because of bradycardia, necessitating reprogramming of pacemaker mode. There was a statistically significant difference in the incidence of atrial undersensing between the two groups, both at predischarge and follow-up visits ($P = 0.026$). Our overall incidence of significant atrial undersensing was comparable to that in the findings of other studies.[3,4,21,22] We have not observed any episodes of pacemaker-mediated or ventricular tachycardia and atrial fibrillation during observation period. The rarity of atrial fibrillation in our study might be related to the protective effect of VDD pacemaker[11] and relatively short follow-up duration. As symptomacy of VDD patients is not strictly related to the frequency of atrial undersensing, it is desirable to avoid any kind of atrial undersensing in single-lead VDD pacemakers. Right-sided VDD implantation is a new idea in achieving this goal.

Limitations

Our study was limited as a result of its reliance on the event counter of pacemaker to evaluate the percentage of AV synchrony. However, a comparative evaluation of sensing function between the groups was done by a combined use of atrial signal amplitude, telemetered ECG, event histogram, sinus rate, spontaneous AV conduction, and clinical data at each visit. Reliability of this combined evaluation has been noted previously.[23] Our study duration is relatively short, explaining partially no case of atrial fibrillation and sinus node dysfunction during follow-up. However, the stability of postimplantation atrial sensing measurements has been documented previously.[15]

Conclusions and Clinical Implications

In accordance with previous studies, single-lead VDD pacing is an effective and reliable pacing option in selected patients with AV block and normal sinus node function. Implant side has significant influence on improving atrial sensing performance and maintaining AV synchronization in single-lead VDD pacemakers. Right-sided VDD has a much better atrial sensing function, both in short- and long-term evaluations. Therefore, right-sided implantation can be recommended to improve the performance of VDD pacing. However, confirmation of these findings in a larger patient population is reasonable to determine general implantation guidelines.

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