

Immediate and Mid-Term Safety and Efficacy of Single Lead VDD Pacemakers for Patients with Atrioventricular Block and Normal Sinus Node Function—A Single Centre Experience

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Abstract

Introduction: Single lead atrial synchronous ventricular pacing (VDD) is increasingly being used in place of conventional dual chamber pacing (DDD) for patients with atrioventricular block and preserved sinus node function. Compared to the latter, VDD pacemakers provide similar haemodynamic benefits derived from atrial synchronous pacing, with the added benefit of an easier implant procedure. **Objective:** To review the use, safety and efficacy of VDD pacing in a single tertiary referral centre. **Materials and Methods:** A review of all patients with atrioventricular block and normal sinus node function implanted with a VDD pacemaker over a 2-year period at a local tertiary cardiac referral centre. Data on complications, atrial sensing performance and maintenance of atrioventricular synchrony during implant and at subsequent follow-up visits were obtained from a prospectively maintained registry and analysed. **Results:** Forty-one patients (17 males, 24 females) with a mean age of 72 ± 9 years received VDD pacing for various forms of high-grade atrioventricular block. The average implantation time was 46.8 ± 17.1 minutes, and a pneumothorax in 1 patient was the only complication. Electrical measurements at implantation and subsequent follow-up visits revealed an initial rapid decrease in atrial signal amplitude (mean atrial P wave at implant 3.1 ± 1.1 mV, predischARGE 1.9 ± 1.3 mV) which began to stabilise after 3 months, reaching a mean atrial P wave value of 1.3 ± 0.3 mV at 24 months. The atrial sensing performance (percentage of atrial synchronous ventricular complexes) was 97% over a mean follow-up period of 9.9 months. Four patients (10%) developed paroxysmal atrial tachyarrhythmias. Sinus node dysfunction was not observed in any of our patients during the follow-up period. **Conclusion:** In patients with atrioventricular block and preserved sinus node function, single lead VDD pacing is safe and effective in maintaining a physiological atrial synchronous pacing mode.

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Key words: Atrial synchronous pacing, Atrioventricular block, Pacemaker, VDD pacing

Introduction

In patients requiring a cardiac pacemaker for any indication, the ideal goal of therapy is to achieve atrioventricular (AV) synchrony. This replicates the normal cardiac contraction sequence and is better tolerated with fewer associated complications in the long term.^{1,2} In patients with coexisting heart block and sinus node dysfunction, such physiological pacing can be achieved using a conventional dual chamber pacing system with leads implanted in both the atrium and ventricle to sense and pace both chambers in a synchronous fashion. However, in patients with heart block but normal sinus node function, a dual chamber pacemaker is effectively functioning only as a ventricular pacemaker with an atrial sensing function, as the atrial lead is merely sensing the sinus node activity and triggering ventricular pacing.

To circumvent the insertion of an atrial lead in such patients, the single lead atrial synchronous ventricular pacing (VDD) system was developed to provide both ventricular pacing and sensing as well as atrial sensing using a single lead only. This single lead, which is positioned like a normal ventricular lead, has additional free-floating electrodes within the proximal part of the lead body which can be positioned in the right atrium for atrial sensing (Fig. 1). As atrial pacing is not required, direct contact between the atrial electrodes and the atrial wall is unnecessary.

Single-lead VDD pacing preserves AV synchrony with its associated haemodynamic advantages³⁻⁵ and compared to conventional dual chamber pacing, it avoids the insertion of an additional atrial lead, is cheaper, and makes the implanter's work simpler and easier. It is hence increasingly

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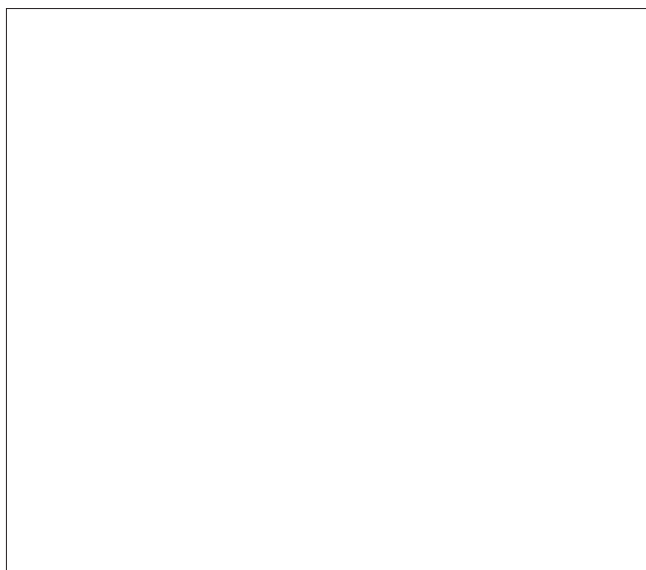


Fig. 1. Chest X-ray of a VDD pacemaker with 2 atrial sensing electrodes (white arrow heads) positioned near the atrial wall for optimal results.

popular. The objective of this review is to evaluate our experience with VDD pacing over a 2-year period with emphasis on its safety and efficacy.

Materials and Methods

Patient Selection

Between June 1998 and June 2000, 41 consecutive patients receiving a single lead VDD pacemaker for symptomatic or high-grade AV block were included in this retrospective study. Sinus node dysfunction was excluded before the procedure by observing an average baseline sinus rate of >70 beats per minute over 24 hours and absence of sinus arrest on inpatient telemetric monitoring or ambulatory electrocardiographic analysis.

Pacemakers and Leads

Four different VDD pacemaker systems were used: Thera #8968 VDD (25 patients), Sigma 303 VDD (5 patients) and Kappa 701 VDD (5 patients) generators with Model #5038 leads (31 patients) or Capsure 5032 (4 patients) leads from Medtronic (Minneapolis, MN, USA) and Pulsar VDD generators with Model #4341 leads (6 patients) from Guidant (St Paul, MN, USA).

Implantation

All implantations were performed under local anaesthesia with intravenous sedation using midazolam and fentanyl. After cannulation of either the cephalic or subclavian vein, the lead was inserted through a peel-away introducer and positioned under fluoroscopic guidance. Once the ventricular tip was positioned satisfactorily with acceptable ventricular pacing and sensing thresholds, the proximal part of the lead with the free-floating atrial dipole electrodes

was adjusted to locate the site of the optimal atrial signal, which was defined as the site of both maximal and stable P wave amplitude as measured through the atrial channel of the pacing system analyser (Medtronic, Minneapolis, MN). A P wave signal amplitude of at least 2mV was deemed optimal, and this was achieved in all but 4 patients. When atrial mapping was completed and the optimal atrial signal obtained, the lead was anchored and connected to the pulse generator and the final position confirmed via fluoroscopy. After the procedure, the patients were usually observed overnight and discharged the following day.

The maximal atrial and ventricular sensing signals and ventricular stimulation threshold as determined by the pacing system analyser were recorded. The implantation time was taken as the time from the first injection of local anaesthetic to complete closure of the incision. Selected clinical and electrical data were entered into a prospectively maintained database.

Follow-up

As per institutional protocol, sensing and threshold measurements were determined at implant and 1 day later before discharge, and during follow-up visits at 2-4 weeks, 3 months and at 6-monthly intervals thereafter. The atrial sensing threshold was determined by decreasing the atrial sensitivity until loss of atrial tracking occurred with the patient in a supine position. All pacemakers were programmed to the highest atrial sensitivity setting. Patients were also assessed for complications during the routine follow-up visits, as well as for evidence of sinus node dysfunction and atrial fibrillation or other forms of atrial tachyarrhythmias from routine electrocardiograms (ECG), 24-hour Holter recordings and the presence of frequent mode switching episodes during pacemaker interrogation. In patients who had Holter monitoring performed during the follow-up period, the Holter recordings were scrutinised for evidence of atrial undersensing or oversensing.

Data Analysis

All continuous variables were expressed as mean $\pm$ standard deviation.

Results

Patient Characteristics

Between June 1998 and June 2000, a total of 41 patients (17 males, 24 females) with a mean age of 72 ± 9 years (range, 40 to 88 years) received a VDD pacemaker. From our Cardiac Data Bank, this represented 17% of the total number of pacemakers implanted over the same time period; the other types of pacemakers implanted were DDD/DDDR (89 patients–37%) and VVI/VVIR (109 patients–46%).

The most common indication was symptomatic complete heart block (76%), with other forms of symptomatic high-grade AV block making up the rest. None of the patients had evidence of sinus node dysfunction as defined from ECG, telemetric or ambulatory electrocardiographic recordings. However, 1 patient was known to have very infrequent episodes of paroxysmal atrial fibrillation.

Implantation

The pacing lead was introduced via the cephalic venous cut-down technique in 14 patients (34%) and subclavian vein puncture in the remaining 27 patients (66%). All pacemakers were implanted in the left pectoral region. The average implantation time was 46 ± 17 minutes (range, 20 to 90 minutes). One patient developed a pneumothorax after subclavian puncture which required needle aspiration. No other complications were associated with implantation.

Electrical Measurements at Implantation

The standard electrical measurements, including P wave amplitudes, R wave amplitudes, ventricular pacing thresholds, lead current and lead resistance, were recorded at implantation. The mean values for our patient population are shown in Table I. These values are within the acceptable range of values for the respective pacemaker systems.

Follow-up

The patients were followed up for a mean period of 9.9 months (range, 1 to 28 months). The atrial sensing thresholds at various time intervals, as manifested by the strength of the P wave signals, are shown in Figure 2. In the 1-day interval from implantation to discharge, there was a steep reduction in the P wave amplitude which then stabilised during subsequent follow-up of up to 24 months. The atrial sensing performance, as manifested by the percentage of atrial synchronous ventricular complexes during pacemaker interrogation, was 100% at implant, 99% (range, 95% to 100%) before discharge, and 97% (range, 68% to 100%) at the last follow-up visit. All patients remained in VDD pacing mode as of their last visit.

During follow-up, 4 patients (10%) developed atrial tachyarrhythmias. One developed persistent atrial flutter

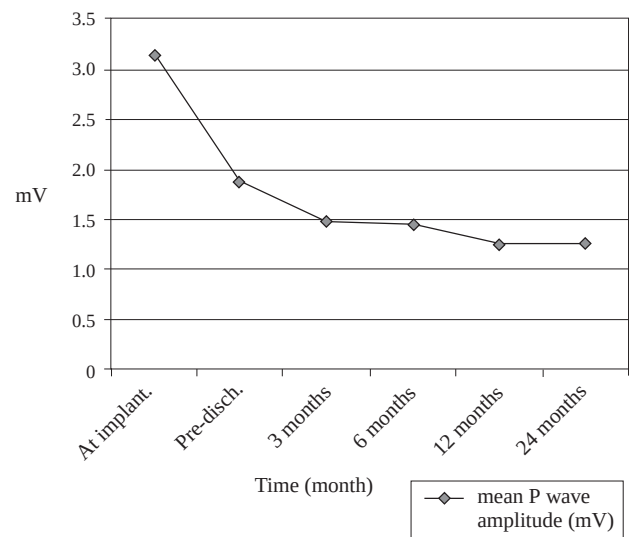


Fig. 2. Mean P wave amplitude during follow-up.

after 12 months requiring pace termination. He has since remained well. Two others had paroxysmal atrial flutter which occurred infrequently, and the single patient who had paroxysmal atrial fibrillation pre-implantation was found to have frequent mode switching episodes, indicating the presence of a paroxysmal tachyarrhythmia. None of the patients had evidence of sinus bradycardia.

Eleven out of the 41 patients had 24-hour ambulatory electrocardiographic monitoring performed during follow-up. Review of the recordings did not show any evidence of undersensing (not sensing the P wave that was present and pacing the ventricle independently) but there were 2 cases of oversensing which were easily corrected by appropriate reprogramming.

Discussion

Physiological pacing with atrioventricular synchrony is the optimal treatment for patients with AV block and normal sinus node function. This form of atrial-triggered ventricular pacing has been shown to improve exercise capacity, reduce the incidence of pacemaker syndrome and the development of atrial fibrillation with its concomitant embolic complications.^{1,2}

Although VDD pacemakers have been available since the late 1970s, it was not until the last 10 years that extensive clinical experience was gathered. This was mainly due to the advent of better leads and devices.^{6,7} In addition to its advantage of maintaining AV synchronised pacing in patients with AV block and normal sinus node function, the implantation technique is relatively straightforward and similar to that for a single lead ventricular pacing system. This makes the VDD system an attractive option as implantation is simpler and faster in comparison to a conventional dual chamber pacing system.

TABLE I: ELECTRICAL MEASUREMENTS AT IMPLANTATION

Measurements	Mean	Range
i) Right atrial P wave amplitude (mV)	3.14 ± 1.14	0.5 - 5.4
ii) Right ventricular R wave amplitude (mV)	12.4 ± 5.9	0.28 - 2.3
iii) Right ventricular pacing threshold (mV)	0.35 ± 0.13	0.2 - 0.7
iv) Right ventricular lead current (mA)	0.52 ± 0.30	0.16 - 1.4
v) Right ventricular lead resistance (Ω)	716.7 ± 166.8	498 - 1140

From our Cardiac Data Bank, the majority of the DDD/DDDR pacemakers implanted in our institution over the same time period, was for Sick Sinus Syndrome (61%). Only 28 patients (31%) out of the 89 patients who had DDD/DDDR pacemakers implanted were those with atrioventricular block and preserved sinus node function. The reasons for choosing VDD pacemakers over DDD/DDDR pacemakers in this group of patients were firstly, a DDD pacemaker, in this particular group of patients, would essentially be functioning in VDD mode as atrial pacing was not required. Secondly, a VDD pacemaker with only 1 lead was technically easier and faster to implant than a DDD pacemaker which required the insertion and positioning of 2 separate leads. Our mean implantation time for a VDD pacemaker was 46.8 ± 17.1 minutes. This is faster than the mean implantation time for a dual chamber which is usually at least 1 hour in published studies comparing VDD and DDD pacing.⁸ Lastly, a VDD pacemaker would be slightly cheaper than a DDD pacemaker.

Previous studies have shown that there is usually a 2-fold reduction in atrial signal (P wave) amplitude between implantation and subsequent follow-up.^{4,9} The reasons for this observed decrease in the atrial signal amplitude may be due to the use of different equipment in the sampling methods and also to the positional stability of the atrial dipole electrodes at rest and during movement. The minimal atrial signal during implantation should therefore be at least 2 mV at rest in the supine position. In our study, the mean P wave amplitude was 3.14 and only 4 patients did not achieve an atrial amplitude signal of more than 2 mV during implantation.

Reliable sensing from the free-floating atrial electrodes is crucial for successful VDD pacing. During follow-up, the mean atrial signal in our patients decreased most significantly in the first 6 months after which it stabilised subsequently. This result is comparable to other studies.^{4,6} The reasons for these changes have not been determined. A possible cause may be the different methods of measurement used during implantation (the external pacing system analyser) and follow-up (the pulse generator and programmer). In addition, the free-floating atrial electrodes may be affected by movement and postural changes.¹⁰ Other contributory factors like lead flexibility, the length of the loop in the superior vena cava, the size of the atrium and the movement of the mediastinum during breathing and postural changes may also play a part. Thus, the stability of the position of the atrial bipole electrodes rather than the absolute amplitude of the atrial signal may be a better marker for reliable atrial sensing in the first few months. With time, the lead may become encapsulated at points of prolonged contact with the atrial and ventricular

walls. The atrial electrodes thus affected have a reduced degree of free movement within the atrial cavity, leading to reduced variations and fluctuations of the P wave signals. This may explain the stabilisation of P wave amplitude with time, as seen in our patients.¹¹

Despite the reduction in P wave amplitude over time, the atrial sensing performance remained satisfactory. A mean of 97% of paced beats were atrial synchronous complexes at the last follow-up. The maintenance of synchronous AV pacing over time is an important feature of dual chamber pacing, and VDD pacing has been shown to have comparable efficacy.⁸

Paroxysmal atrial tachyarrhythmias were detected in 4 patients (10%) a few months post implantation. Since mode-switching was available in all the pacemakers used, rapid tracking of the atrial flutter or fibrillation did not pose a problem. This incidence is not higher than that observed in the general elderly population which is around 3% to 10%.¹² Sinus node dysfunction was not observed during the follow-up period. This corresponded with previously published studies, in which the risk of sinus node disease developing in patients with AV block was found to be low. In 155 patients with complete AV block and normal sinus node function at baseline, Wiegand et al¹³ found that the cumulative incidence of sinus node disease was 0.65% per year, of which only 0.2% were symptomatic. In the same study, the cumulative incidence of atrial fibrillation was 0.2%.

Conclusion

In summary, single lead VDD pacing system provides physiological pacing without the need to implant two leads and a dual chamber pulse generator. This is cost effective and time saving. The complication rate is low, not more than what one would expect from a single chamber pacemaker. The atrial signal did decrease after implantation but subsequently stabilised after the first six months, and more importantly, did not affect the maintenance of physiological AV synchronous pacing. Hence, in patients with AV block but normal sinus node function, physiological pacing can be achieved efficiently, safely and effectively in a single lead VDD system. Nevertheless, it is still possible to improve on the present VDD lead systems to further increase the stability of atrial sensing over time to make this an even more attractive pacing modality.

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