Clinical results with single lead VDD pacing

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Abstract

Objective: For patients with atrioventricular block single lead atrial synchronous ventricular pacing (VDD) may have advantages compared to conventional dual chamber pacing (DDD) since it eliminates the need for an atrial lead. The purpose of this study was to investigate the clinical performance of a novel VDD pacemaker and the reliability of atrial sensing via the ‘floating’ atrial electrode. Methods: 31 patients (10 females; age 64 ± 13 years) underwent an implantation of a VDD pacemaker system (Intermedics UNITY). The patients were analyzed with regard to implantation parameters, complications and postoperative atrial sensing performance using the diagnostic data of the pacemaker memory. The mean follow-up was 6.3 (1–18) months.

Results: The implantation procedure did not differ from that of conventional single chamber pacemakers. Dislocation of a ventricular electrode was the only complication observed. The P wave at implantation was 1.6 ± 0.9 mV and dropped to 0.9 ± 0.4 mV at predischarge. During follow-up the atrial sensing threshold remained stable. The atrial sensing performance (percentage of atrial synchronous ventricular complexes) after reprogramming the highest atrial sensitivity was 99.7%. Two patients (6%) developed atrial fibrillation. 29 patients (94%) remained in VDD mode as primarily intended. Conclusions: From these results it is concluded that VDD pacing represents an excellent alternative in patients with atrioventricular block and intact sinus node function. The atrial sensing was found to be reliable. © 1997 Elsevier Science B.V.

Keywords: Cardiac pacing; AV synchrony; Single lead concept; VDD pacing

1. Introduction

The implantation of a DDD pacemaker still represents the gold standard in the treatment of patients with symptomatic atrioventricular block. However, technical problems related to the atrial lead placement, higher complication rates in comparison with VVI pacemakers and loss of atrial sensing are limitations of this method. High degree AV block represents more than 50% of the pacing indications throughout Europe, whereas two thirds of the patients are still treated with VVI-pacemakers [7]. With the introduction of the VDD pacemaker systems using a single pass lead in patients with normal sinus node function an alternative was opened with regard to simplification of the implantation procedure as well as the improved quality of atrial signal processing.

The purpose of this study was to evaluate the practicability and reliability of a new VDD pacemaker with regard to problems encountered with the perioperative course. Furthermore, the stability of the atrial signal detection via the floating electrode and the percentage of AV synchrony had been examined.
2. Patients and methods

2.1. Patients

From March 1994 to August 1995 31 patients (10 females) with a high degree AV block underwent an implantation of a new VDD pacemaker at the University Hospital, Regensburg. The mean age was $63.9 \pm 13$ (range 20–86) years. Unless informed consent was refused, every elective patient with symptomatic second ($n=9$) or third ($n=22$) degree AV block and normal sinus node function was included in this study. Sinus node function was evaluated by means of 24 h electrocardiograms and treadmill exercise tests. Patients with coexisting sinus node dysfunction or history of atrial tachycardias were excluded.

The underlying cardiac disorders were coronary artery disease in 11 patients, and dilated cardiomyopathy in 2 patients. 10 patients previously underwent cardiac surgery (coronary artery bypass grafting $n=2$, aortic valve replacement $n=4$, mitral valve replacement $n=3$, combined aortic and mitral valve replacement $n=1$). In 8 patients no underlying heart disease was existent.

2.2. Pacemaker system

The VDDR pacemaker system consists of the single pass lead (‘Unipass’ 424-04, Intermedics, Angleton, TX), and the multiprogrammable pacemaker (‘Unity’ 292-07). The lead couples the ability of atrial sensing with ventricular sensing and stimulation. The triaxial lead consists of two diagonally opposed atrial platinum–iridium electrodes. Each electrode is considered a unipole with the pacemaker case as the common ground electrode. The signals from each dipole are combined and differentially filtered to enhance local P wave amplitude while rejecting far field signals (‘differential bipolar sensing’). Thus, the highest possible atrial sensitivity is 0.1 mV. Leads with different separations (11, 13 and 16 cm) between the ventricular tip and the atrial bipolar are available.

Due to the exercise response option in cases of permanent atrial fibrillation as well as chronotropic incompetence VVIR stimulation is possible. During intermittent atrial tachycardia, the maximum pacing rate is determined by the conditional ventricular tracking limit, which is designed to protect against inappropriate responses to high atrial rates not due to exercise.

2.3. Implantation technique and measurements

The implantation of the single pass lead was performed by either cutting down the cephalic vein and direct application or using the Seldinger technique for the subclavian vein. In all patients a lead with a tip to dipole distance of 13 cm was chosen. After placement of the electrode tip the usual pacing thresholds and R wave amplitudes were determined. P wave amplitudes were measured during normal and deep breathing after the diagonal atrial bipole (DAB) was positioned in a visually optimal position (high right atrium, Fig. 1). Then, by adjusting the intravascular length of the lead, the best atrial sensing was determined and the lead was fixed. During implantation the Intermedics pacing system analyzer (PSA) was used, which has similar atrial filter settings as the pacemaker. In case of atrial signal amplitudes < 1.0 mV a differential amplifier adapter (DAA 1401, Cardiac Control Systems, Palm Coast, FL) was used.

2.4. Follow-up

During follow-up by telemetry of the pacemaker P and R wave amplitudes and pacing thresholds were determined following a fixed scheme on the first postoperative day, after 4 weeks and in further 3 months intervals. Measurements were made with the patient resting in a supine position as well as at forced respiration using a regular programmer (RX 2000 Graphics, Intermedics). The intra-cardiac signal was recorded by increasing the atrial sensing threshold up to a maximum of 1.6 mV. Loss of sensing was determined by online ECG recording. The Holter option of Fig. 1. X-ray showing the correctly placed floating bipole in the high right atrium.
Fig. 2. Intracardiac ECG as recorded with the pacemaker during muscle provocation (arrow). The atrial signal detected by the floating bipolar is marked ‘P’ (P wave). The ventricle is paced and the spike is marked ‘V’. There is a correct atrial driven ventricular stimulation without myo-potential influence.

the pacemaker permits an easy verification of correct AV-synchronous pacing by means of beat to beat analysis. If an atrial event is not sensed by the floating electrode, it will be considered as ‘atrial undersensing’ because of the ventricle is either paced or sensed without a foregoing P wave. The number of QRS complexes with AV synchrony was divided by the total number of QRS complexes, and the value is given in % (‘atrial sensing performance’). While recording the atrial intracardiac electrogram (Fig. 2), muscle provocation maneuvers like homolateral hand pressing (‘hand grip test’) with the highest programmable atrial sensitivity were performed. In addition, in cases of retrograde conduction the VA conduction time was measured.

2.5. Programming

The nominal pacemaker values were kept 24 h. During the postoperative pacemaker check the systems were reprogrammed in order to obtain the maximum gain of atrial triggered QRS complexes. Reprogramming included: increasing the upper frequency limit, programming the highest possible atrial sensitivity (0.1 mV) and activation of the adaptive AV delay. To avoid asynchronous ventricle stimulation the lower rate limit was programmed to 35–40 bpm. In cases of retrograde conduction the postventricular atrial refractory period (PVARP) was prolonged.

2.6. Statistics

Values given in the text are mean ± 1 S.D. Statistical analysis was performed using SPSS software for Windows. Normal distribution was tested by means of Lillifors modification of the Kolmogorow-Smirnow test. Student’s t-test was used for comparison of mean values. For analysis of the relationship between the P wave amplitudes and the atrial sensing performance a correlation analysis was performed. P < 0.05 was considered significant.

3. Results

3.1. Intraoperative findings

In 22 patients (71%) the 6.6 French single pass lead was introduced into the cephalic vein. Nine patients (29%) required puncture of the subclavian vein using the Seldinger technique. The preferred site of implantation was the right pectoral (28 versus 3). Mean X-ray duration was 5.4 ± 4.2 min. Pacing threshold was 0.5 ± 0.16 V at a fixed pulse width of 0.5 msec; impedance was 490 ± 114 Ohms. The sensing threshold was 8.6 ± 2.9 mV for ventricular and 1.6 ± 0.9 mV for atrial signals.

3.2. Follow-up

No technical complications related to surgery were observed in any of the patients. In one case the lead had to be replaced due to dislocation of the ventricular electrode 4 weeks after implantation. This patient showed stable atrial sensing despite a loss of capture in the ventricle.

During the mean follow-up of 6.3 months (1–18 months) 2 patients (6.4%) developed chronic atrial fibrillation requiring a switch to VVIR mode. Both patients previously had mitral valve replacement for mitral insufficiency. One patient with diffuse coronary artery disease and poor left ventricular function developed intermittent atrial tachycardia. During medical conversion the pacemaker was programmed to back up VVI mode and later reprogrammed to VDD. In another patient the rate response option had to be activated due to sinusbradycardia. The remaining 27 pacemakers had no change in pacing mode during follow-up. Altogether 29 of the 31 patients (94%) finally showed the VDD mode as primarily intended.

The time course of ventricular pacing and sensing threshold showed no abnormal findings (Table 1). The atrial sensing threshold dropped from 1.6 ± 0.9 mV intraoperatively to 0.9 ± 0.4 mV on the first postoperative day (P = 0.002). During follow-up the mean P wave amplitudes remained stable (Fig. 3). The intra-individual deviations of the atrial signal were 37.7 ± 24.3%; values varied from 0.2 mV to > 1.6 mV. There was no correlation between maximum P wave amplitude and maximum per cent of AV synchrony (r = 0.03).
Table 1  
Ventricular pacing and sensing thresholds, time flow chart

<table>
<thead>
<tr>
<th></th>
<th>OP</th>
<th>1 day</th>
<th>1 month</th>
<th>3 months</th>
<th>6 months</th>
<th>9 months</th>
<th>12 months</th>
<th>15 months</th>
<th>18 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pacing (V)</td>
<td>0.5 ± 0.2</td>
<td>0.6 ± 0.2</td>
<td>0.8 ± 0.4</td>
<td>0.9 ± 0.4</td>
<td>1.0 ± 0.6</td>
<td>0.9 ± 0.4</td>
<td>1.0 ± 0.3</td>
<td>1.0 ± 0.2</td>
<td>1.0 ± 0.2</td>
</tr>
<tr>
<td>Sensing (mV)</td>
<td>8.6 ± 3.0</td>
<td>9.2 ± 2.8</td>
<td>8.6 ± 3.4</td>
<td>9.2 ± 2.6</td>
<td>9.3 ± 2.8</td>
<td>10.3 ± 2.9</td>
<td>9.6 ± 2.5</td>
<td>10.2 ± 0.8</td>
<td>7.5 ± 0.7</td>
</tr>
</tbody>
</table>

n = 33 1 31 23 17 10 8 7 3 3

Mean values ± S.D. intraoperatively (OP); predischarge (1 day), after 1, 3, 6, 9, 12, 15, and 18 months (n = No. of patients).

All patients were reprogrammed within 24 h after implantation in order to achieve optimal AV synchrony. 23 patients enrolled the second visit after 4 weeks. The percentage of AV synchrony in these patients was 99.7% after reprogramming. The Holter function of the pacemaker revealed in 17 patients a complete (100%) AV synchrony and in 6 patients a 99% atrial sensing performance after reprogramming. All patients were discharged with the highest atrial sensitivity setting of 0.1 mV. Two cases of myopotential tracking were recorded during follow-up. After decreasing the atrial sensitivity to 0.3 mV no more myopotential sensing occurred and the patients maintained a 100% AV synchrony.

4. Discussion

The hemodynamic and nonhemodynamic advantages of maintaining atrioventricular synchrony as compared to single chamber pacing are widely accepted [5,6,12–15,17,20,21,23]. Atrial tracking modes such as VAT, VDD or DDD are preferred in the treatment of symptomatic AV block. Despite this the number of unphysiological VVI systems is high because of the inconvenience of the additional atrial lead (longer implantation procedures, longer radiation time, more expensive systems). A further disadvantage is the higher complication rate with atrial leads. Bernstein and Parsonnet describe in the World Survey 1993 [3] a twofold higher 4 weeks complication rate with atrial leads in comparison to ventricular leads (2.9 versus 1.5%). Brownlee et al. [4] report on a complication rate for atrial leads of 11% over a 6 year period (dislocation, loss of sensing, lead fracture).

Another lead related problem is atrial sensing failure in DDD pacemakers. It has been shown by Froehlig et al. [9,10] that exercise diminished the P wave amplitude up to 49% of the resting signal. Loss of atrial sensing was observed in 44% of these patients. This was confirmed by the results of Zitzmann et al. [24] in 34 patients with ‘optimal’ DDD program mode. Almost two thirds of the patients showed intermittent atrial undersensing.

Single lead VDD pacing offers an opportunity for AV sequential pacing without the complexity of atrial electrodes. Our results show that the implantation procedure is similar to that of conventional VVI pacemakers. The introduction of the 6.6 French lead via V. cephalica was possible in 71% of the patients. In 29% puncture of the V. subclavia was necessary. Although there are three available distances between the atrial sensor and the ventricular tip we only used the 13 cm distance without complications even in enlarged right ventricles. The only complication observed during the postoperative course was a ventricular lead dislocation causing loss of capture but without atrial sensing failure. After lead replacement the patient kept a stable VDD mode with 100% AV synchrony. Previous studies with other VDD systems demonstrated serious problems with broken VDD electrodes [11] and pacemaker mediated tachycardias due to far field ventricular potential sensing [1,5,16], but this was not encountered in our study.

Two patients (6.4%) developed chronic atrial fibrillation (CAF) during follow-up. In an italian multicenter study 2.1% of the patients treated with VDD systems developed CAF [1]. Parravicini et al. [19] reported on a CAF incidence of 7% in 35 patients. Although a comparison is not useful in view of the different follow-up times the proportion of 6.4% CAF in our study group is relatively high. However, the large number of organic heart diseases (both patients

Fig. 3. P wave amplitude detected by the floating atrial bipolar (mean values ± S.D. intraoperatively, day one, 1, 3, 6, 9, 12, 15, and 18 months postoperatively).
with CAF previously had mitral valve surgery) accounts for the atrial tachyarrhythmias. The ultimate goal of VDD pacing is reliable and stable P wave sensing and thus preserving AV synchrony. According to the manufacturers recommendation we initially accepted P values only above 0.5 mV intraoperatively. But this could not be maintained in some patients who showed lower atrial sensing thresholds at implantation and a stable atrial sensing performance during follow-up. The drop of atrial sensing on the first postoperative day in our group was due to different methods of measurement. Postoperative measurements allowed values only up to 1.6 mV whereas intraoperative values were unlimited. As our data show, reliable P wave sensing is possible via the floating electrode. The resting P wave signal seems to have no influence on the atrial sensing performance. The high quality of atrial signal detection and differentiation becomes clear with the atrial sensing performance of 99.7% in our study. In two similar studies with other VDD systems the percentage of AV synchronous QRS complexes was distinctly below 90% [8,19]. More recent studies revealed a P wave tracking of 94.7% [2], 99.8% [18] and 99.1% [22].

Although rare, sick-sinus syndrome may develop in patients with AV block (binoxal disease). There is also some evidence in the literature that atrial pacing reduces the rate of atrial arrhythmias [6,8,15,21]. As the atrium cannot be paced this may be the major drawback of the VDD mode. Several ongoing prospective randomized studies address this topic. Up to now a careful patient selection excluding patients with sinus node dysfunction and intermittent atrial fibrillation is required.

4.1. Limitations

As 99.7% of atrioventricular synchrony is based on the pacemaker memory utilizing the intracardiac signal there is little likelihood of sensing atrial activities of other origins. Therefore our results have to be proved by Holter ECG recordings. This, together with a standardized exercise test will be subject of an ongoing study.

Although the mean follow-up was 6.8 months, only data for 10 patients with a longer follow-up than 3 months were available. The percentage of patients developing chronic atrial fibrillation therefore may be underestimated.

5. Conclusions

It has been shown in the present study that implantation of a new VDD single lead pacemaker was possible in all patients with symptomatic AV block and intact sinus node function without any technical complications. P wave sensing was reliable and consistent with the floating atrial lead. The AV synchrony as recorded by the pacemaker memory was independent of the resting P wave amplitude and yielded almost 100%. Thus VDD pacing offers an excellent alternative to conventional DDD stimulation.

References


