

A Comparison of Single-Lead VDD Pacing with Two-Lead DDD Pacing in Patients with AV Block

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Summary

In patients with atrioventricular (AV) block and normal sinus node function, physiologic AV-synchronous pacing can be achieved with two-lead DDD as well as single-lead VDD systems. The presented study has two goals: first, to test the safety and reliability of single-lead VDD pacemakers compared with two-lead systems in a prospective and randomized manner over the long-term course of 4 years; and second, to document the incidence of atrial tachyarrhythmias in three pacing forms; Group A: two-lead pacemaker in DDD mode; group B: two-lead pacemaker in VDD mode; group C: single-lead VDD pacemaker in VDD mode. So far, 250 patients (mean age 68.9 ± 12.0 years, 47.2 % female) have been enrolled and randomized into the three groups. There are no differences in gender, age, left-ventricular function, and atrial diameter among the groups. The mean follow-up period is 25.7 ± 15.9 months; 60 patients have reached the 4-year follow-up. The implantation time was significantly shorter in the single-lead VDD mode: Group A = 74.9 ± 35.0 min; group B = 64.8 ± 37.6 min; group C = 54.1 ± 33.5 min (A vs C, $P < 0.001$; A vs B, $P < 0.083$; B vs C, $P < 0.057$). The X-ray exposure was also clearly shorter in group C: A = 9.7 ± 7.2 min; B = 8.7 ± 6.2 min; C = 6.3 ± 4.9 min (A vs C = $P < 0.0011$; B vs C = $P < 0.01$; A vs B = $P < 0.35$). The AV synchronicity was similar in all groups: A = 92.7 ± 0.06 %; B = 95.8 ± 0.05 %; C = 99.2 ± 0.01 %. The cumulative incidence of atrial fibrillation during the follow-ups was: A = 9.1 %; B = 7.4 %; C = 6.2 % (A vs B = $P < 0.96$; A vs C = $P < 0.15$; B vs C = $P < 0.57$). In regard to their AV-synchronous behavior, the single-lead VDD systems are equal to the two-lead systems. However, they also offer the advantage of shorter implantation and X-ray exposures. The incidences of atrial tachyarrhythmias currently only show a tendency toward differences; a final answer to this question can only be provided at the end of the total follow-up period.

Key Words

Dual-chamber pacemaker, VDD system, single-lead electrode, atrial tachyarrhythmia

Introduction

In the last years, VDD therapy with one lead (single-lead VDD) has increasingly become an alternative to the established and accepted therapy form of DDD pacing in patients with symptomatic atrioventricular (AV) block and chronotropic competence [1-3]. Many clinical trials have shown that single-lead systems offer a reliable and safe therapy for patients with normal sinus node function and AV conduction disturbances [4-7].

The presented VDD versus DDD study has two goals: first, to test the reliability of single-lead VDD pacing prospectively in the long term; and second, to document the incidence of atrial tachyarrhythmias in the different pacing forms.

The literature states a value of 4 – 15 % for the incidence of atrial tachyarrhythmias during long-term DDD pacing [3,8]. The mechanisms that induce atrial arrhythmias are still the subject of investigation.

Among many other aspects, the mechanical and electrical irritation of the atrial myocardium appears to be an important factor. Given a correct lead position, the mechanical stress to the atrial myocardium caused by a VDD lead is considered to be low when compared with a fixed electrode. Furthermore, a VDD pacemaker does not pace in the atrium, thus excluding electrical interactions between sensing and pacing. Consequently, it could be expected that VDD and DDD pacemaker systems have a different influence on the development of atrial tachyarrhythmias.

This prospective study compares the reliability of a VDD pacemaker system with that of a DDD system in a long-term study over a total of 4 years. To this end, the patients were randomized into three groups. The patients in the first group (A) received a two-lead system (atrial and ventricular lead) with a DDD pacemaker programmed to the DDD mode, which results in mechanical as well as electrical stress to the atrium. In the second group (B), the patients received the same two-lead-pacemaker system, but programmed to VDD. Thus, the atrium was only mechanically stressed. The patients of the third group (C) were implanted with a single lead and a VDD pacemaker, mostly excluding atrial stress, be it mechanical or electrical. Aside from confirming advantages of a single-lead VDD system already known from other studies, such as shorter times of implantation and X-ray exposure, the presented study aimed at comparing the long-term complication rates. Differences between the systems were mainly expected in the incidence of permanent atrial tachyarrhythmias.

After the patients have now surpassed on average half of the total follow-up period intended for this study, the initial results of the not yet concluded study will be presented in the following.

Materials and Methods

The ongoing research, which started in 1996, is carried out as a prospective, randomized, multicenter study with 22 participating clinics in nine countries. Altogether, 300 patients will be enrolled into the study.

Patients

Patients with an indication for implantation of an antibradycardia pacemaker requiring ventricular pacing were included. The patients had to exhibit an AV or intraventricular conduction disturbance and normal

sinus node function. The latter was verified by a pre-operative recording of the sinus rate, whereby the mean resting rate should be ≥ 80 beats/min. Patients with a resting sinus rate between 70 and 80 beats/min were also admitted if an atropine test (1.0 mg) led to a sinus rate increase of at least 25 % to more than 90 beats/min.

Patients with documented atrial tachycardias, atrial flutter, or atrial fibrillation were not included in the study. Further exclusion criteria were an anti-arrhythmic therapy of the classes I, III, or IV, an unstable angina pectoris or a known severe cardiac disease, or other diseases with a life expectancy of less than 4 years. All patients were informed about the content, purpose, and risks of the study, and gave their written consent to participate.

Groups

The patients were divided into three groups according to a previously defined randomization scheme (random list):

- Group A: two-lead system and DDD pacemaker programmed to the DDD mode;
- Group B: two-lead system and DDD pacemaker programmed to the VDD mode;
- Group C: single lead and VDD pacemaker programmed to the VDD mode.

The respective mode was not reprogrammed except for clinical reasons.

The implants listed in the following were used within the framework of the study. The respective numbers of patients implanted with the listed device types are stated in parentheses.

Pacemaker Systems

Various DDD and VDD pacemakers, manufactured by Biotronik, Germany, were used:

- Group A: Physios TC 01 (75 patients), Actros D (six patients), or Dromos DR with inactive rate-responsive function (one patient);
- Group B: Physios TC 01 (76 patients), Actros D (four patients), or Dromos DR with inactive rate-responsive function (two patients);
- Group C: Dromos SL (85 patients) or Actros SLR with inactive rate-responsive function (one patient).

Leads

In groups A and B, any suitable unipolar or bipolar atrial and ventricular leads with passive or active fixation were used. The leads were from various manufacturers. In group C, single leads of the types SL 60/11 (four patients), SL 60/13 (65 patients), SL 60/14 (one patient), and SL 60/15 (15 patients) were implanted (all from Biotronik).

Pre-Implantation and Implantation

Prior to implantation, the usual patient-related data (age, gender, etc.) were recorded, and an echocardiographic examination was performed. It determined the diameters of the right and left atrium and the left-ventricular function. The operation time and the X-ray exposure were noted in the protocol aside from the usual intraoperative measurements.

Follow-up

The follow-ups are performed every 6 months and are concluded after 4 years. During each follow-up, the atrial and ventricular thresholds, the impedance, and the amplitudes of the filtered P- and R-waves are determined using a standard procedure. In addition, the minimum and maximum atrial amplitudes are measured in supine position with an intracardiac electrogram. Furthermore, any complications that have occurred in the patients, pacemakers, and leads are documented. In case of an electrocardiographic diagnosis of atrial fibrillation, the arrhythmia is classified as paroxysmal (spontaneous conversion within 48 hours), persistent (lasting > 48 hours and requiring antiarrhythmic medication or cardioversion for conversion to sinus rhythm), or permanent (no conversion possible or intended). The event counters and trend monitors of the pacemakers are analyzed, especially in regard to the question of whether the atrial rate was constantly higher or lower than the programmed basic rate or the programmed upper tracking rate, respectively. The AV synchronicity was also recorded. Changes in the pacemaker parameter settings, in particular the pacing mode, were documented.

Statistics

Two statistical test methods were applied for data analysis, depending on the kind of data comparison: Student's t-test (two-tailed P-value) was used for the comparison of two population means, and the chi-square test was used for independent samples.

Results

So far, 250 patients, 132 of them male (52.8 %) and 118 female (47.2 %), have been included in the study and randomized into the three study groups:

- Group A = 82 patients (32.8 %), 42 of them male (51.2 %) and 40 female (48.8 %);
- Group B = 82 patients (32.8 %), 44 of them male (53.7 %) and 38 female (46.3 %);
- Group C = 86 patients (34.4 %), 46 of them male (53.5 %) and 40 female (46.5 %).

Data from the 4-year follow-up (= end of study participation) are available for 60 patients (19 patients in group A, 16 patients in group B, and 25 patients in group C).

The mean follow-up period of all analyzed follow-ups is 25.7 ± 15.9 months (24.9 ± 15.4 months in group A, 24.9 ± 16.2 months in group B, and 27.3 ± 16.4 months in group C).

At the time of pacemaker implantation, the mean age of the patients was 68.9 ± 12.0 years (69.7 ± 10.0 years in group A, 68.2 ± 10.7 years in group B, and 68.6 ± 14.5 years in group C). The youngest patient was 14 years old, and the oldest was 93.

The ECG indication of the patients was a second degree AV block in 37.8 % of the cases, and a third degree AV block in 57.3 %; the percentage of patients with intra-ventricular conduction disturbances was 4.9 %.

The echocardiographic examination of the left-ventricular function showed a reduced ejection fraction (< 60 %) averaging $44.2 \% \pm 6.8 \%$ in a total of 51 patients; the remaining patients showed a well-preserved left-ventricular pump function. The right atrium had a mean diameter of 37.8 ± 6.7 mm, and the left atrium of 41.5 ± 6.3 mm. The echocardiographic measurement results for the individual groups did not differ.

Significant differences were found between the three groups in some basic parameters measured during implantation and/or follow-up. Thus, the total time of implantation was 74.9 ± 35.0 min in group A, 64.8 ± 37.6 min in group B, and 54.1 ± 33.5 min in group C (Figure 1). The difference between group A and group C is significant ($P < 0.001$). There is a tendency toward a difference between group A and group B ($P < 0.083$) and between group B and group C ($P < 0.057$).

The time of X-ray exposure was 9.7 ± 7.2 min in group A, 8.7 ± 6.2 min in group B, and 6.3 ± 4.9 min in group

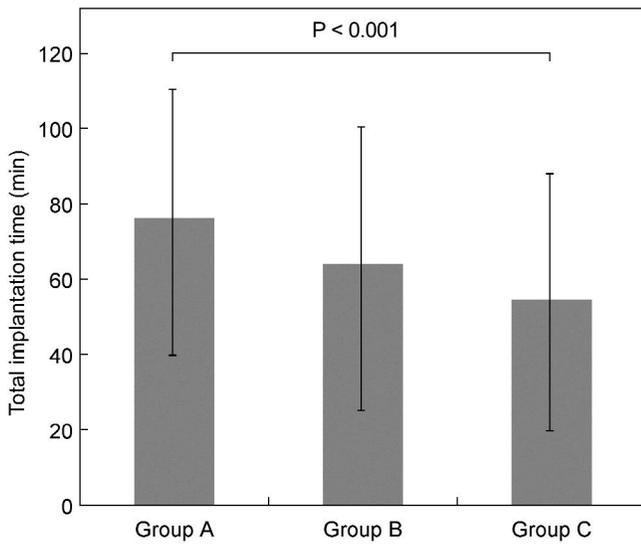


Figure 1. Total time of implantation. Mean and standard deviation. Student's *t*-test; two-tailed.

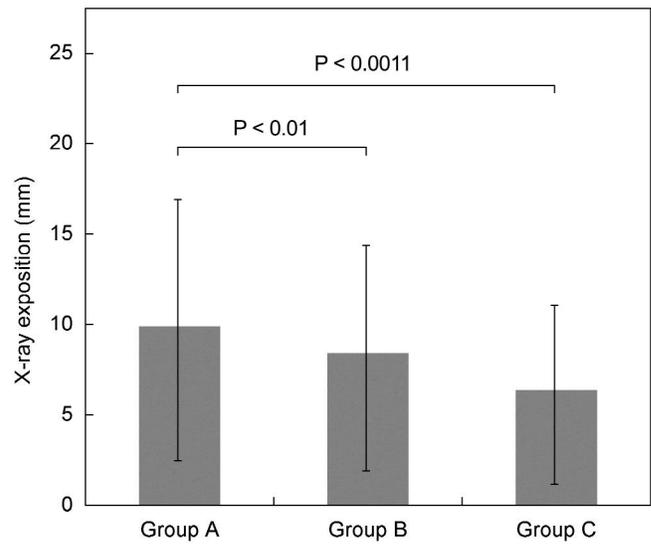


Figure 2. Time of X-ray exposure. Mean and standard deviation. Student's *t*-test; two-tailed.

C (Figure 2). The differences between group A and group C ($P < 0.0011$) and between group B and group C ($P < 0.01$) were significant. There was no significant difference between group A and group B ($P < 0.35$).

The percentage of patients with regular AV synchronicity (defined as $> 95\%$ AV-synchronous pacing in the event monitor) in the three groups was determined from the data of the respective follow-ups and is shown in Table 1. On average, $92.7 \pm 0.06\%$ of the patients in group A, $95.8 \pm 0.05\%$ in group B, and $99.2 \pm 0.01\%$ in group C had regular AV synchronicity.

In most follow-ups, the minimum and maximum atrial amplitudes in the supine position are significantly smaller in group C than in groups A and B. Table 2 shows the mean values and standard deviation, as well as the minimum and maximum in relation to the group mean values for the minimum and maximum atrial amplitude

measured in the supine position from the follow-ups for the three groups. With 1.0 ± 0.2 mV and 1.7 ± 0.3 mV, respectively, the maximum and minimum atrial amplitudes were clearly lower in the group C patients than the values for the patients in groups A and B.

Most of the other measurements of atrial and ventricular parameters (amplitude, impedance, threshold, etc.) did not show significant differences among the three groups. So far, reprogramming to the VVI mode has only been documented for a few patients. Permanent atrial fibrillation was stated as the reason for reprogramming:

- Group A: four patients in VVI mode (starting at the 12-, 30-, 36-, and 48-month follow-up, respectively);
- Group B: one patient in VVI mode (starting at the 12-month follow-up);
- Group C: zero patients in VVI mode.

Group	6-month	12-month	18-month	24-month	Patients (%)				Mean \pm SD
					30-month	36-month	42-month	48-month	
A	94.7	97.0	98.1	97.6	91.7	88.0	81.0	93.3	92.7 ± 0.06
B	94.6	95.5	93.2	97.5	100.0	100.0	100.0	85.7	95.8 ± 0.05
C	97.3	98.4	98.1	100.0	100.0	100.0	100.0	100.0	99.2 ± 0.01
Total	95.5	96.9	96.6	98.4	97.6	96.3	94.4	94.4	96.3 ± 0.01

Table 1. Percentage of patients with regular AV synchronicity ($> 95\%$). SD = standard deviation.

	Group	P-wave amplitude (mV)		Range
		Mean	SD	
Maximum value	A	3.7	0.7	2.7 - 4.4
	B	3.1	0.4	2.6 - 3.7
	C	1.7	0.3	1.4 - 2.1
Minimum value	A	1.8	0.3	1.4 - 2.2
	B	1.6	1.5	0.8 - 5.2
	C	1.0	0.2	0.7 - 1.4

Table 2. Maximum and minimum atrial amplitudes in the supine position; mean, standard deviation (SD) and range from the mean group values of eight follow-ups.

On the basis of the data collected to date, no significant differences have been found among the three groups in regard to the incidence of atrial fibrillation, the cumulative incidence of atrial fibrillation related to all follow-ups so far, as well as the general incidence in patients to whom at least the 42-month follow-up is available. At this stage, data analysis has not yet differentiated between paroxysmal, persistent, and permanent atrial fibrillation.

Table 3 shows the cumulative incidence of atrial fibrillation from all follow-ups. In the analysis, the sum of all follow-up intervals with atrial fibrillation was juxtaposed to the sum of all follow-up intervals without atrial fibrillation for the three groups, using all so far existing follow-ups of all patients. The percentage of follow-up intervals with atrial fibrillations was 9.1 % in group A, 7.4 % in group B, and 6.2 % in group C. While the chi-square test showed some tendencies for differences (A vs C), there were overall no significant differences between the groups (A vs B: $P < 0.96$; A vs C: $P < 0.15$; B vs C: $P < 0.57$).

Group	Total no.	Follow-up		With AF (%)
		No. without AF	No. with AF	
A	341	310	31	9.1
B	229	212	17	7.4
C	385	361	24	6.2

Table 3. Cumulative incidence of atrial fibrillation (AF). No. = number.

The results of the group comparison from the analysis of the general incidence of atrial tachyarrhythmias in patients for whom at least the 42-month follow-up is available are shown in Table 4. For this procedure, the patients from each group were divided into three sub-groups each:

- patients in whom atrial fibrillation was documented in none of the follow-ups;
- patients in whom atrial fibrillation has been documented so far only in one follow-up in the course of the study; and
- patients in whom atrial fibrillation has been documented in more than one follow-up.

The chi-square test showed no significant differences among the groups ($P < 0.66$).

Discussion

A survey of the current literature in the field of pacemaker therapy for patients with symptomatic, higher-degree AV block and chronotropic competence shows that there are quite a lot of studies about single-lead VDD pacing, most of them are ongoing [9-15]. They range from retrospective studies to prospective randomized multicenter trials, and from projects that evaluate only one respective single-lead VDD system to studies that compare VDD therapy using one lead with the established therapy form of DDD pacing that uses an atrial and a ventricular lead. To our knowledge, the presented study is the only multicenter, prospective, randomized study that includes a patient group with two-lead DDD pacemakers programmed to the VDD mode in the comparison of the single-lead VDD mode versus the two-lead DDD mode. This study design has the great advantage of allowing a distinction of two-lead systems, between a purely mechanical stress brought about by an atrial lead and an electrical stress caused by the interaction between sensing and pacing. The results of the general patient data (gender distribution, mean follow-up period, patient age) and the parameters recorded during the echocardiographic examination (ejection fraction, right atrial and left atrial diameter) show a homogeneous distribution in the three groups A, B, and C, thus confirming the randomization scheme that was used.

As could be expected due to the easier implantation procedure for single-lead VDD systems, a significant

Group	Without AF	Patients		Total
		With 1 AF	With > 1 AF	
A	15 62.2 %	5 21.7 %	3 13.0 %	23 100 %
B	4 66.7 %	1 16.7 %	1 16.7 %	6 100 %
C	24 75.0 %	7 21.9 %	1 3.1 %	32 100 %

Table 4. General incidence of atrial fibrillation (AF). Incidence in patients for whom at least the 42-month follow-up is available. Both the absolute and relative values are shown.

reduction in the times of implantation and X-ray exposure was achieved when compared to the implantation of two leads in a DDD system. Similar significant results have also been found in other prospective "VDD versus DDD" studies [12,13,16].

According to the currently available data, the percentage of patients with regular AV synchronicity is highest for the single-lead system (group C) and reaches on average 99 %. This can be explained by the stable P-wave sensing in the long-term course. As expected, the minimum and maximum atrial amplitudes in the supine position are significantly smaller in group C than they are in group A and group B in most follow-ups. Nevertheless, the range of the atrial amplitude in the supine position in group C is clinically acceptable, especially if the maximum atrial sensitivity is programmed. Using a long-term ECG, other studies have also proven AV-synchronous pacing averaging 99 % for VDD systems [5,7,17]. In a review article, Nowak [2] describes the results of two non-randomized, long-term trials, according to which AV-synchronous pacing was maintained in over 90 % of the patients after two and five years with VDD and DDD systems. He comments that further insights into this question should be expected from the not yet concluded, prospective, randomized, comparative studies. By looking at the data gained so far from this study, we can answer this question in that here AV-synchronous pacing was maintained clearly in more patients even after four years, at least for the group with the VDD system.

The question of whether the long-term incidence of newly occurring atrial fibrillation is higher for two-lead DDD or single-lead VDD systems has not yet been clearly answered. On the one hand, atrial pacing

in the DDD mode could have a stabilizing influence on the sinus rhythm; on the other hand, atrial pacing itself can induce atrial fibrillation, e.g., by mechanically and electrically stressing the atrium with the atrial lead or if a stimulus falls into the vulnerable phase of the atrium in the case of atrial undersensing.

So far, published first results of the still ongoing, prospective, randomized VDD-DDD comparative studies have found no significant differences between the two systems in regard to the incidence of atrial fibrillation, though atrial tachyarrhythmias occurred usually somewhat less frequently in the respective patient groups with single-lead VDD than in the DDD groups [15,18].

Permanent atrial fibrillation requires reprogramming to the VVI(R) mode. In regard to the frequency of VVI(R) mode programming, the literature cites highly differing values. A direct comparison of the various study results is difficult due to the differences in the respective follow-up periods or patient numbers: The values regarding a necessary reprogramming of single-lead VDD to VVI range from 3.2 to 11.7 % [4-6,19-22], whereas reprogramming from the DDD mode to VVI pacing took place for up to 15.5 % in the long-term course [3,8]. As a limiting factor, it should be stated that mostly mixed patient populations (AV block and sick sinus syndrome) were involved in the DDD studies with long-term follow-up; therefore, the higher incidence of VVI programming due to atrial fibrillation in DDD systems must be interpreted with caution. To date, the published results of the ongoing, prospective, randomized VDD-DDD comparative studies have not found any significant differences between VDD and DDD in regard to reprogramming to the VVI mode [10].

Since only patient data from about half the planned total follow-up period on average are available so far from the presented study, the trends toward differences in the incidence of atrial tachyarrhythmias, on the one hand, and in the necessity of VVI pacing, on the other hand, may reach statistical significance after analysis of the entire 4-year follow-up period of all included patients.

Conclusion

Single-lead VDD pacing ranks equally with the two-lead systems in regard to P-wave sensing, AV synchronicity, and ventricular lead characteristics in the

long-term course of four years. However, it has the advantage of a significantly shorter implantation time and X-ray exposure. Currently, only a tendency toward differences between the individual pacing forms can be shown for the incidence of permanent atrial tachy-arrhythmias. For a final answer to this question, the conclusion of the entire follow-up must be awaited.

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