Pacemaker Programming in Clinical Practice: Three Months Interim Results from the Philos Register

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Summary

Today's pacemakers offer an entire range of programming functions that enable physicians to individually tailor their patients' cardiac treatment. However, comparatively little has been known about the process of pacemaker programming in typical clinical practice. During the post-marketing surveillance "Philos Register", a total of 300 patients from around the world who have been implanted with a Philos pacemaker will be monitored over a time period of one year. The results of a preliminary analysis of the 3-month follow-up data for 76 patients show that the pacemaker's various programming functions were activated with differing frequency (between 3% and 97%), whereby a significant positive correlation was found to exist between a programming function's frequency of use and its benefit (physician analysis via a rating system) (correlation coefficient = 0.89, two-sided significant at p-value < 0.01). A similar result was found for the frequency of use of the pacemaker's various diagnostic memory functions (statistics): the frequency of use varied between 12% and 97%, and there was also a significant positive correlation to the benefit (correlation coefficient = 0.69, two-sided significant at p-value < 0.01). These first results stemming from the preliminary analysis of a small group of patients suggest that the multifaceted programming and statistics functions of a modern pacemaker differ considerably in their uses and benefits. In order to optimize pacemaker use in clinical practice, a reduction in the most essential programming and statistical functions can be considered for the generally preset default functions.

Key Words

Pacemaker, programming functions, diagnostic memory functions, benefit

Introduction

Today's pacemakers offer a number of programming functions that allow in many cases an individually optimized pacemaker therapy for each patient. Due to the multitude of different programming functions that are available for a particular therapy in the commercially offered pacemaker models, it is often difficult for the attending physician to find the optimal programming, especially if there are no safe and proven recommendations based on clinical data.

In most cases where new pacemaker algorithms were the object of clinical studies, the general efficacy of a new therapy was tested. Usually, the standard setting of the respective programming function was compared to a control group, in which the programming function was deactivated [1-3]. In contrast, there are only relatively few prospective, randomized studies that have attempted to find the optimal setting of a programming function that allows the best possible therapy for a majority of the patients [4-6].

So far, comparatively little is known about the approach when programming pacemakers in the regular clinical practice: What rules do attending physicians follow in programming the pacemakers of their patients? Do they orient themselves to scientifically

tested programming recommendations? Or do they usually just stay with the manufacturer's factory settings in most cases? What role does the personal experience of the physician and previous clinical examinations of the patient play? Are there attempts to find the pacemaker programming that is optimal for the individual patient, and what is the clinical basis (e.g., patient history, additional examinations) that can assure such optimal programming? Or is it sufficient in most cases to just achieve an improvement in the patient's health with the pacemaker and to reprogram only if problems occur?

The Philos Register aims at answering a number of these questions. In this post-marketing surveillance, a total of 300 patients worldwide, who have been implanted with a Philos DR, Philos D, or Philos SLR (Biotronik, Germany) pacemaker, are to be observed over a period of one year. As part of the usual pacemaker follow-ups, it will be recorded which settings of the programming functions were changed, and how much of a benefit the individual programming functions offer from the view of the attending physician. Furthermore, the use of the pacemaker-recorded statistic data (diagnostic memory functions) is documented, especially their benefit for diagnosis and therapy.

This paper presents the results of an interim analysis that evaluated the data of the patients who have undergone at least the 3-month follow-up.

Materials and Methods

The Philos Register is a prospective, multicenter, international post-marketing surveillance. Of a total of 300 patients planned, 249 patients have so far been enrolled in the time period between September 2001 and December 2002. Each patient will participate in the study for one year, with the scheduled follow-up intervals following the generally applied guidelines for pacemaker therapy [7]: implantation; pre-hospital discharge, 3-month, 6-month, and 12-month follow-up.

In the Philos Register, patients were and are included who have a pacemaker indication according to the currently used guidelines [7,8] and have been or will be implanted with a pacemaker of the type Philos DR, D, or SLR. The pacemakers can be operated as single-chamber or dual-chamber devices. There are no exclusion criteria. There are also no requirements regarding the chosen atrial and ventricular leads. The programmer for the follow-ups is obligatory: PMS 1000 with the software module SWM 1000 Version B-K00.V.A/2 or higher (Biotronik). The pacemakers are programmed according to the needs of the patients: no guidelines are provided as part of this post-marketing surveillance. The following data are recorded in the context of the Philos Register:

- Inclusion: date of birth, gender, weight, NYHA class, symptom(s), ECG indication(s), etiology(ies), ejection fraction (facultative), medication.
- Implantation: date, duration, implants, respective implantation position, intraoperative measurements (P- and R-wave amplitudes, pacing threshold, impedance), retrograde conduction (facultative).
- Pre-hospital discharge, 3-, 6-, 12-month follow-ups: date, duration, NYHA class, ejection fraction (facultative), measurements (P- and R-wave amplitudes, pacing threshold, impedance), retrograde conduction (facultative).

In addition, the following statements by the investigators are documented as part of the follow-ups:

- Programming functions (benefit, settings, reason for setting): dynamic AV delay, AV hysteresis, AV repetitive hysteresis, AV scan hysteresis, mode conversion, mode switching, overdrive, PMT protection, minimum PVARP, automatic lead check (atrium and ventricle), arrhythmia detection recording (ADR).
- Diagnostic memory functions (statistics): evaluation of the usefulness of the statistics, especially of their use in diagnosis and therapy (event counters, atrial rate histogram, ventricular rate histogram, A/V rate trend, tachy episode trend (graphic, mode switching counter, tachy episode protocol), AT/AES classification, AES vs. atrial rate, AES coupling interval, VES classification, VES vs. atrial rate, VES coupling interval, sensor rate histogram, activity report, P-wave trend, R-wave trend, A/V impedance trend). Documentation and evaluation of extraordinary events in the arrhythmia detection recording (ADR).

For the statistic analysis of the listed results, the correlation coefficient according to Spearman-ρ (two-sided) was used, applying the statistics software SPSS for Windows (release 10.0.5, SPSS, USA).

Results

The following results are based on data from a total of 77 patients, for whom case report forms from the implantation to at least the 3-month follow-up were

available at the beginning of the evaluation. One patient died 2.7 months after implantation; thus, the analysis of the 3-month follow-up data is based only on 76 patients. If not noted otherwise, the results are stated as mean ± standard deviation.

Results from Inclusion/Implantation

The patients were included into the Philos Register in 17 clinics from 7 countries (Table 1). On average 4.5 ± 7.7 patients were enrolled at each clinic. Of the 77 patients, 42 were men (55%) and 35 women (45%). The mean age of the patients was 71 ± 12 years at the time of implantation. The mean weight was 77 ± 16 kg. 52 patients (68%) were receiving cardiac drugs at the time of their inclusion into the Philos Register. In Table 2, the number and percentage of patients are shown sorted according to cardiac drug categories.

Table 3 lists the documented indications for a pacemaker therapy according to the code from the European Pacemaker Registration Card (Version 7, 1996) and shows the number and percentage of patients to whom a particular code was assigned. In the category ECG Indication, 54% had a conduction disturbance (AV block or bundle branch block), and 41% had sick sinus syndrome. The most frequently diagnosed symptom was syncope (87%). For the etiology, a code of the reporting groups Unspecified or Unknown was stated in 62% of the patients.

The overall implantation duration was 51 ± 27 min. The implanted pacemakers were 67 Philos DR (87%), 3 Philos D (4%), and 7 Philos SLR (9%). In the atrium, 73 bipolar (95%) and 4 unipolar (5%) leads were implanted, whereas the ratio of 38 bipolar (49%) to 39 unipolar (51%) leads in the ventricle was almost balanced. In 91% of the cases, leads by Biotronik were used: Polyrox (37%), Y (26%), Elox (11%), TIR (8%), Merox (5%), SL (5%), YP (4%), Synox (2%), PE (2%), and TIJ (2%). The remaining leads came from Medtronic (4%), St. Jude Medical (3%), Pacesetter (1%), and Teletronics (1%). The intra-operative measurement values were within the normal range. These results will be shown as part of a later publication, which will be based on data of a much larger number of patients.

Results from 3-month Follow-up

Figure 1 shows a comparison of the NYHA class percentages between implantation and 3-month follow-up. The mean NYHA class improved from 1.6 ± 0.7 at the time of implantation to 1.3 ± 0.5 at the 3-month follow-up. The various programming functions available for pacemaker therapy in the Philos were used with widely varying frequency. Table 4 shows the number of patients (and the percentage of the total number of patients, respectively) in whom a programming function was or became activated at the time of the 3-month follow-up. In almost all patients (97%), the dynamic AV delay was turned on, it being the only one of the studied programming functions that is already activated in the factory settings. The programming functions mode switching (72%), arrhythmia detection recording (49%), PMT protection (41%), and automatic lead check (ventricle = 32%, atrium = 25%) were also programmed comparatively frequently. In contrast, the three hysteresis functions, minimal PVARP, overdrive, and mode conversion were activated rather infrequently (between 3% and 11%).

Country	Patients	Clinics
Germany	43	4
Brazil	19	6
Slovak Republic	6	2
Israel	4	2
Belgium	3	1
Czech Republic	1	1
Spain	1	1
Total no.	77	17
Mean ± SD	11.0 ± 15.4	2.4 ± 1.9

Table 1. Number of included patients and participating clinics per country. SD = standard deviation.

Cardiac drugs	Patients	
Antihypertensive	39	(51%)
Cardiac glycosides	10	(13%)
Diuretic	8	(10%)
ASS	6	(8%)
Antiarrhythmic	4	(5%)
ACE inhibitor	2	(3%)
Beta blocker	1	(1%)
Other	1	(1%)
Patients with medication	52	(68%)

Table 2. Cardiac drugs. Number of patients and percentage of the total number of patients (n = 77), respectively.

Reporting Group	Code	Proposals	Patients
ECG Indication			
Unspecified	A1	Rhythm unspecified	1 (1%)
Sinus Rhythm	B1	Normal sinus rhythm	2 (3%)
	B2	NSR + abnormal EPS	1 (1%)
AV Block	C1	1° heart block	1 (1%)
	C2	2° heart block unspecified	4 (5%)
	C3	2° heart block Wenckebach	2 (3%)
	C4	2° heart block Mobitz	13 (17%)
	C5	CHB - QRS unspecified	7 (9%)
	C7	CHB - wide QRS	9 (12%)
Bundle Brunch Block	D4	Left BBB	2 (3%)
	D9	RBBB + LAHB + long PR	3 (4%)
Sick Sinus Syndrom	E1	SSS - unspecified	7 (9%)
	E2	SSS - SA exit block	6 (8%)
	E3	SSS - SA arrest	3 (4%)
	E4	SSS - bradycardia	8 (10%)
	E5	SSS - brady/tachy	7 (9%)
	E8	Chronotropic incompetence	1 (1%)
Symptom			
Unspecified	A1	Unspecified (default)	3 (4%)
	A2	Uncoded	1 (1%)
Syncope	B1	Syncope	27 (35%)
	B2	Dizzy spells	31 (40%)
	B3	Bradycardia	9 (12%)
Tachycardia	C1	Tachycardia	1 (1%)
Other	D1	None/prophylactic	1 (1%)
	D2	Dyspnea/heart failure	3 (4%)
	D3	Cerebral dysfunction	1 (1%)
Etiology			
Unspecified	A1	Unspecified (default)	6 (8%)
	A2	Uncoded	4 (5%)
Unknown	B1	Unknown	24 (31%)
	B2	Conduction tissue disease	14 (18%)
Ischemic	C1	Ischemic	19 (25%)
	C2	Post infarction	2 (2%)
Iatrogenic	E1	Surgical complication	1 (1%)
	E3	Ablation	1 (1%)
	E4	Drug induced	1 (1%)
CSS (ANS)	F1	Carotic sinus syndrom	1 (1%)
Other	G1	Cardiomyopathy unspecified	1 (1%)
	G1B	Cardiomyopathy dilated	1 (1%)
	G2	Myocarditis	1 (1%)
	G3	Valvular heart disease	1 (1%)

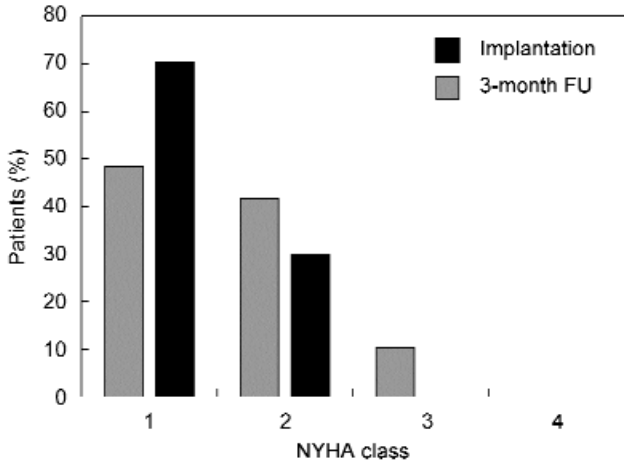

Figure 1. NYHA class distribution at implantation (n = 70 patients) and 3-month follow-up (n = 64 patients). Percentage of all patients for whom the information was provided.

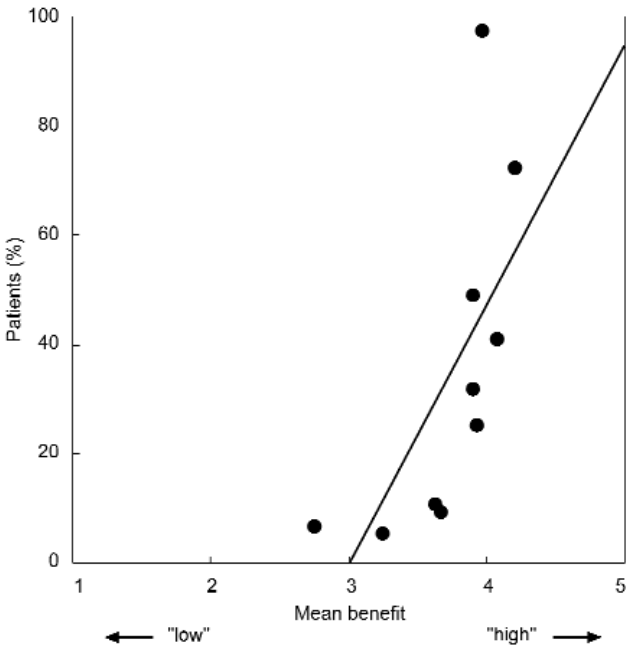

Figure 2. Relationship between the percentage of patients in whom a programming function was activated and the mean benefit with which a programming function was rated by the physicians (N = 10 interrogated programming functions). Correlation coefficient according to Spearman-ρ = 0.89 (two-sided significant at a level of 0.01).

Table 3. Indications for pacemaker therapy. Codes from the European Pacemaker Registration Card (Version 7; this version of the registration card was adopted at the June 20, 1996 EWGCP meeting held in Nice). Number of patients and percentage of the total number of patients (n = 77), respectively.

Programing functions	Factory setting	Patients	Benefit (mean ± SD)
Dynamic AV delay	"low"	74 (97%)	4.0 ± 0.9
AV hysteresis	off	8 (11%)	3.6 ± 1.4
AV repetitive hysteresis	off	4 (5%)	3.3 ± 1.3
AV scan hysteresis	off	5 (7%)	2.8 ± 2.1
Mode conversion	off	2 (3%)	5*
Mode switching	off	55 (72%)	4.2 ± 1.1
Overdrive	off	4 (5%)	1*
PMT protection	off	31 (41%)	4.1 ± 1.3
Minimal PVARP	off	7 (9%)	3.7 ± 0.6
Automatic lead check, atrium	off	19 (25%)	3.9 ± 1.0
Automatic lead check, ventricle	off	24 (32%)	3.9 ± 0.9
Arrhythmia detection recording	off	37 (49%)	3.9 ± 0.9

*Table 4. Activated programming functions of the Philos pacemaker (Biotronik) at the end of the 3-month follow-up: Number of patients and percentage of the total number of patients (n = 76), respectively, in whom the programming function was activated. Mean and standard deviation (SD) of the benefit of the respective programming function, based on all existing ratings by the physicians. Rating on a scale of 1 to 5 (= "low" to "high" benefit) took place only if the programming function was activated. *= rating available for one patient only.*

Statistic	Patients	Benefit (mean ± SD)
Event counters	74 (97%)	4.0 ± 0.9
Atrial rate histogram	72 (95%)	4.0 ± 0.9
Ventricular rate histogram	73 (96%)	4.2 ± 0.8
A/V rate trend	67 (88%)	4.0 ± 0.8
Tachy Episode Trend	54 (71%)	3.9 ± 1.0
a) Graphic	40 (53%)	3.7 ± 0.9
b) Mode switching counter	50 (66%)	3.9 ± 0.8
c) Tachy episode protocol	36 (47%)	3.8 ± 1.0
AT/AES classification	54 (71%)	3.5 ± 1.0
AES vs. atrial rate	37 (49%)	2.7 ± 1.0
AES coupling interval	34 (45%)	2.8 ± 0.8
VES classification	59 (78%)	3.4 ± 1.0
VES vs. atrial rate	36 (47%)	2.6 ± 1.0
VES coupling interval	33 (43%)	3.0 ± 1.0
Sensor rate histogram	15 (20%)	3.0 ± 1.1
Activity report	9 (12%)	2.9 ± 1.3
P-wave trend	58 (76%)	3.4 ± 0.6
R-wave trend	59 (78%)	3.4 ± 0.6
A/V impendance trend	27 (36%)	3.4 ± 0.6
Arrhythmia detection recording	35 (46%)	3.8 ± 1.3

Table 5. Used diagnostic memory functions (statistics) of the Philos pacemaker (Biotronik) during the 3-month follow-up: Number of patients and percentage of the total number of patients (n = 76), respectively, in whom the respective statistic function was used for diagnosis. Mean and standard deviation (SD) of the benefit of the respective statistic, based on all existing ratings by the physicians. Rating on a scale of 1 to 5 (= "low" to "high" benefit) took place only if the respective statistic was used for diagnosis.

The benefit of the various programming functions was ranked at mean values around 3 to 4 on a possible scale of 1 ("low") to 5 ("high"), i.e., the physicians evaluated the benefit on average as between average and good (see Table 4). The scatterogram in Figure 2 shows the relationship between the percentage of patients in whom a programming function was activated and the mean benefit with which the respective programming function was evaluated by the physicians. It shows a significant positive correlation between frequency of use of a programming function and its benefit (correlation coefficient according to Spearman-$\rho = 0.89$, two-sided significant at a level of 0.01).

The diagnostic memory functions (statistics) of the Philos pacemaker, which process the results recorded in the respectively previous time period graphically and in form of tables, were also used with very differing frequency. Table 5 shows the number of patients (and the percentage of the total number of patients, respectively) in whom a diagnostic memory function (statistic) was used for diagnosis at the time of the 3-month follow-up. The most frequently used statistics were the event counters (97%) and the ventricular (96%) or atrial rate histogram (95%). The statistics A/V rate trend (88%), VES classification (78%), and the R-wave (78%) or P-wave trend (76%) were also used comparatively frequently. Ten further diagnostic memory functions were used for diagnosis in about half or up to two thirds of the patients (between 43% to 71%). The statistics A/V impedance trend (36%), sensor rate histogram (20%), and activity report (12%) were diagnostically used in a lower percentage of patients.

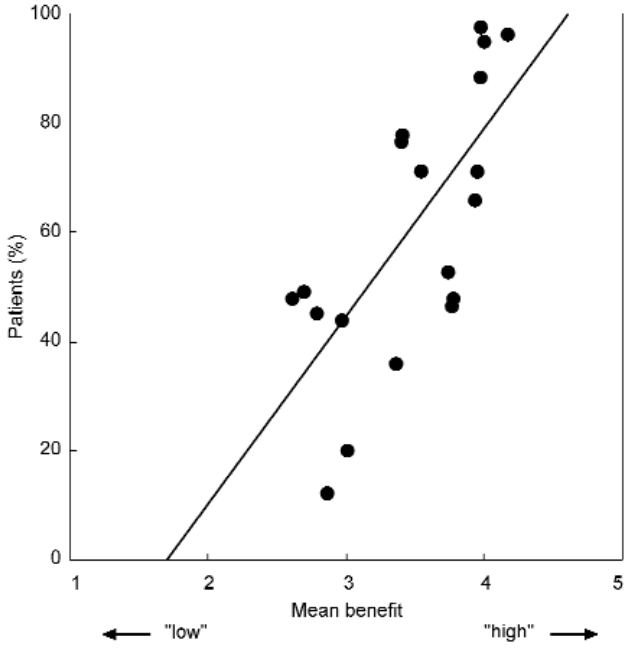

Figure 3. Relationship between the percentage of patients in whom the diagnostic memory functions were used for diagnosis and the mean benefit with which the diagnostic memory functions were rated by the physicians (N = 20 interrogated diagnostic memory functions). Correlation coefficient according to Spearman-ρ = 0.69 (two-sided significant at a level of 0.01).

The benefit of the various diagnostic memory functions was ranked at mean values of around 3 to 4 on a possible scale of 1 ("low") to 5 ("high"), i.e., the physicians evaluated the benefit on average as between average and good (see Table 5). Figure 3 shows the scatterogram for the relationship between the percentage of patients in whom a diagnostic memory function was used for diagnosis and the mean benefit with which the respective diagnostic memory function was evaluated by the physicians. Here, too, there is a significant positive correlation between the frequency of use of a diagnostic memory function and its benefit (correlation coefficient according to Spearman-ρ = 0.69, two-sided significant on the level of 0.01).

Discussion

An ever-increasing number of diagnostic and therapeutic functions can be programmed in modern pacemakers. However, due to the economic situation in the health care system, the physician has just the same or even a lesser amount of time available to program the pacemaker. Consequently, the functions the manufacturers integrate into the pacemakers should be carefully chosen and implemented. This requires analyzing the use of the functions in the daily clinical practice. The Philos Register aims to do just that.

The interim analysis shows that the studied programming and statistic functions were activated with widely varying frequency. It is not surprising that the physicians tended to use options more frequently that they thought to be more beneficial. However, a comparison of the individual parameters also shows differences. Thus, the benefits of the dynamic AV delay and the PMT protection are assessed as about the same (4.0 ± 0.9 versus 4.1 ± 1.3). Nevertheless, the PMT protection was clearly less frequently activated with 41% than the dynamic AV delay (97%). Various reasons are possible. The number of patients who benefit from activating the respective parameter may be different. In case of the dynamic AV delay, its frequent use could also be partially due to the fact that this programming function is already activated in the factory settings.

Non-utilization of a function could also be due to the physician's lack of knowledge about the effect of the activation or, in case of statistic information, about the diagnostic expressiveness. Other reasons might be a cumbersome activation of a programming function or a suboptimal presentation of a statistic value. For instance, the four most frequently used statistics (88% to 97%) among the diagnostic memory functions were exactly those that were first displayed on the programmer printout during the follow-up, whereas the three least frequently used statistics (12% to 36%) also appear only in the last part of the printout. Technical aspects also play a role. For example, the automatic lead check can not be used when the pacing amplitude is programmed to a low value. This certainly contributes to the fact that it was relatively rarely activated despite the assessed high benefit.

After all data have been collected, a detailed analysis of the reasons for using or not using a programming or statistic function is planned. This could lead to consequences for the implementation in future pacemaker generations. For example, if the wish is expressed, it would be a sensible approach for the programmer to fade out rarely used options to make it easier to take in the information at a glance. In the future, frequently used diagnostic data should also be considered when

selecting the information transmitted per Home Monitoring. Since the factory settings are obviously often left unchanged for some of the programming functions, further investigations regarding optimal presettings would be useful.

Conclusion

The interim analysis of the data from the Philos Register does not yet allow a conclusive evaluation of the relevance of the studied diagnostic and therapeutic pacemaker functions in the clinical routine. It is already becoming clear that an existing option is more likely to be used if the treating physician is truly convinced of its benefit.

Participants in the Philos Register

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