Clinical Evaluation of a New Computer Based Expert Management System of Pacemaker Diagnostic Functions

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Summary

The purpose of the study was to assess the clinical utility of a new computer-based expert system for the analysis of the Holter and diagnostic data stored in the pacemaker or implantable cardioverter-defibrillator memory. Thirty pacemaker patients were included in this preliminary evaluation. "Scholiast", the expert system used, is a special software module integrated into an existing Computer Data Manager (CDM 3000). This software allows the data stored in the implanted devices to be transferred during a follow-up control to a personal computer (PC) that is equipped with dedicated data analysis software. The expert system subsequently files the information in its internal memory and begins an analysis using a system of "rules". It evaluates the available diagnostic information, compares it to the limiting values or the reference distributions, and offers hints on determinate findings. At this stage, the system does not deliver advice regarding possible treatment measures. The results of the analysis are arranged clearly in different windows on the PC screen with data, comments, and graphics. This allows for a fast and comprehensive evaluation of the status of both the patient and the pacemaker. The evaluation of the statistical information performed by the "Scholiast" expert system permits the correction and optimization of the pacemaker functions (AV delays, hysteresis option, and rate-responsive sensor functions), in accordance with the real, individual needs of the patient. In conclusion, the preliminary version of the "Scholiast" Expert System appears to be very interesting and helpful. The diagnostic data displayed in the PC are useful for performing a brief clinical evaluation of the patient status and of the device's functions. This automated analysis could be the first step toward a remote control system for heart disease monitoring and prevention, as well as a means of assessing therapeutic efficacy.

Key Words

Expert system, knowledge-based system, computer data manager, pacemaker diagnostic data

Introduction

As the number of available pacemakers continues to grow, new added features are increasing their functionality and complexity. The greater number of statistical functions and stored data requires increasingly more attention and detailed consideration. However, the time and resources required for pacemaker follow-up and adequate use of the stored information are relatively limited (Figure 1). Without a doubt, the possibility of an automatic analysis of the raw interrogated data, based on knowledge-based diagnosis (Figure 2) could be of great help in supporting the physician's decisions. A Computer Data Manager system (CDM 3000, Biotronik, Germany), integrated with a special software module including the Expert System "Scholiast" was developed to meet this challenge.

Scholiast is a prototype for a knowledge-based system intended to help physicians with the analysis of diagnostic data that have been stored in the pacemaker

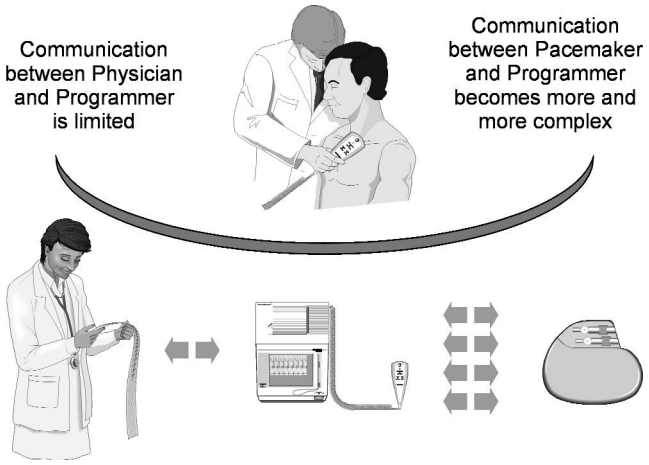


Figure 1. The follow-up situation today.

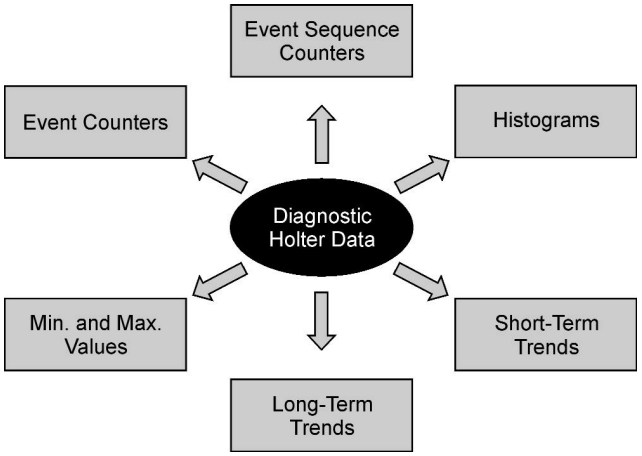


Figure 2. Major contents of diagnostic Holter data.

memory ("Holter data") and made accessible during follow-up examinations of pacemaker patients. To achieve this, Scholiast uses a system of "rules" to evaluate the available diagnostic information, compare these with the limiting values or the reference distributions, and then offer hints on determinate findings. At this stage, the system does not offer advice regarding possible countermeasures.

This system of rules was tested for the first time in a clinical evaluation involving a group of patients. In this preliminary phase of evaluation, in order to appraise as comprehensively as possible the potentials and limitations of the system, this prototype provides both conclusions and the reasoning behind these conclusions. The physician can therefore judge the accuracy of both the conclusion as well as the underlying reasons (motivation). He can also contribute with further comments and rules.

Objective of a Clinical Evaluation

The expert system's practical value for the physician depends decisively on the completeness, the accuracy, the practical relevance, and the other qualitative attributes of its clinical expertise, which is stored as the system of rules. The main aim of the clinical evaluation, which is currently underway, is to assess, complete, and expand the system of rules, which had not been tested previously in a clinical setting. Aside from the system of rules, this clinical evaluation is also intended as a critical exploration of all the other aspects of the expert system, such as its ease of use (ergonomics), the function of all software modules, and the general functionality. Additional comments made by the users will also be taken into consideration for further assessment.

The first phase of the clinical evaluation comprises the following steps:

- Verification (examination of the consistency, completeness, and accuracy of the system of rules, as well as of the further quality attributes, such as its differentiation, its expressiveness, its efficacy, and its avoidance of cycles and redundancy);
- Validation (quality and efficacy of the system as a whole, comprising all the components with respect to the clinical problem); and
- Estimation of the system functionality and ease of use.

A complete estimation of the clinical benefit will not be possible in the framework of this evaluation process. Nevertheless, in a subsequent phase of the study, physicians will be asked to estimate the clinical benefit of this type of system.

Materials and Methods

For this part of the clinical evaluation, the CDM 3000 software with the special "Scholiast" module was installed in a personal computer (PC) at our pacemaker clinic. The PC was then connected to the programmer PMS/TMS 1000 (Biotronik) via a serial interface. For the clinical assessment, we used the data stored in the pacemakers implanted in our clinic (in this phase only from Logos and Actros model generators, all

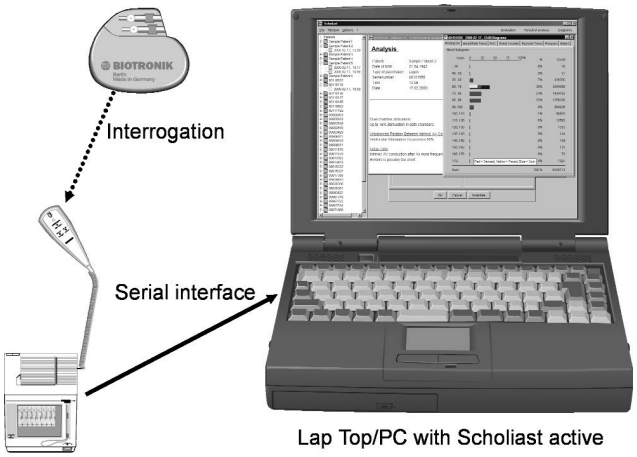


Figure 3. Components and data flow of the Computer Data Management (CDM) 3000 based expert system. The CDM 3000 software with the special "Scholiast" module was installed in a laptop computer connected to the programmer PMS/TMS 1000 (Biotronik) via a serial interface.

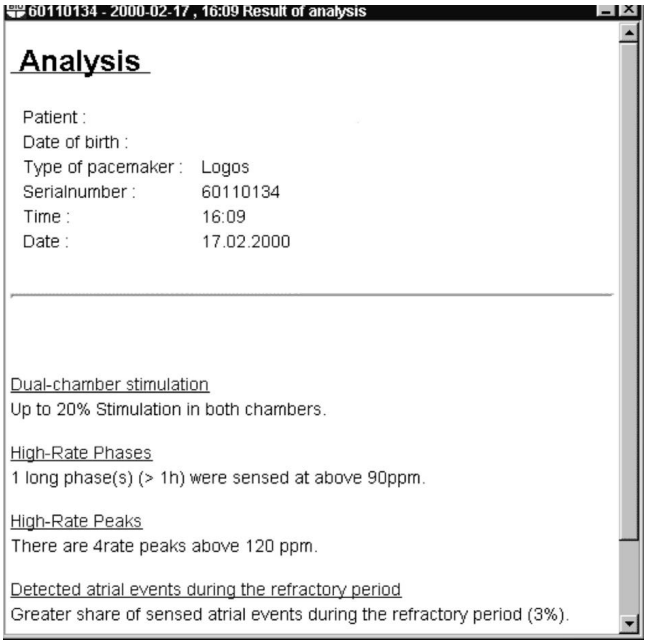
products of Biotronik). We performed the scheduled follow-up according to standard procedure, interrogating the implanted pacemaker. After successful interrogation and printing of the results, the programmer transmited all the interrogated pacemaker data (information regarding the patient, program parameters, statistical data, etc.) to the PC via the serial cable. The interrogated data are then downloaded to the CDM 3000 database and to the expert system. At this point, the system started the automatic analysis and the data were displayed on the computer screen (Figure 3). In the narrow left column, the data sets are arranged in a tree-like structure, with all the follow-up information, stored according to the respective patients (rendered anonymous) and then sorted by date and time (Figures 3). As in a standard PC software, the data sets may be accessed via a pull-down menu. After successful analysis, the new data set will be stored and will appear in the left part of the window in a tree-like structure. Simultaneously, the results of the analysis will be displayed on the working screen on the right. The working screen contains three types of windows (Figure 4):

- Analysis window: This window comprises the results of the analysis, arranged in orderly fashion and provided in a clear and comprehensible way, with hypertext links to further background information;
- Graphics window: This window displays all Holter data compiled in graphic form, together with a list of all pacemaker programming parameters distributed on several registers, which may be displayed by clicking the corresponding tabs;
- Evaluation window (which will be removed in the final version of the software): This window repeats the results of the analysis in combination with the corresponding motivations or rationale on one registry for every result, each combined with a corresponding input for the physician's assessment of the analysis results.

The software provides multi-user capability, with the possibility of granting specified individuals different levels of access to pacemaker and patient data.

Preliminary Results

Thirty patients were included in this preliminary evaluation (Table 1). Both the CDM 3000 and the Expert System turned out to facilitate both access and use. The results of the data analysis were clearly arranged in different windows on the screen, with data, comments, and graphics, allowing a fast and comprehensive evaluation of the status of both the patient and the pacemaker. The evaluation of the obtained statistical information allowed the correction and optimization of the pacemaker's functional parameters according to the real, individual needs of


60110134 - 2000-02-17 , 16:09 Result of analysis

Analysis

Patient :
Date of birth :
Type of pacemaker : Logos
Serialnumber : 60110134
Time : 16:09
Date : 17.02.2000

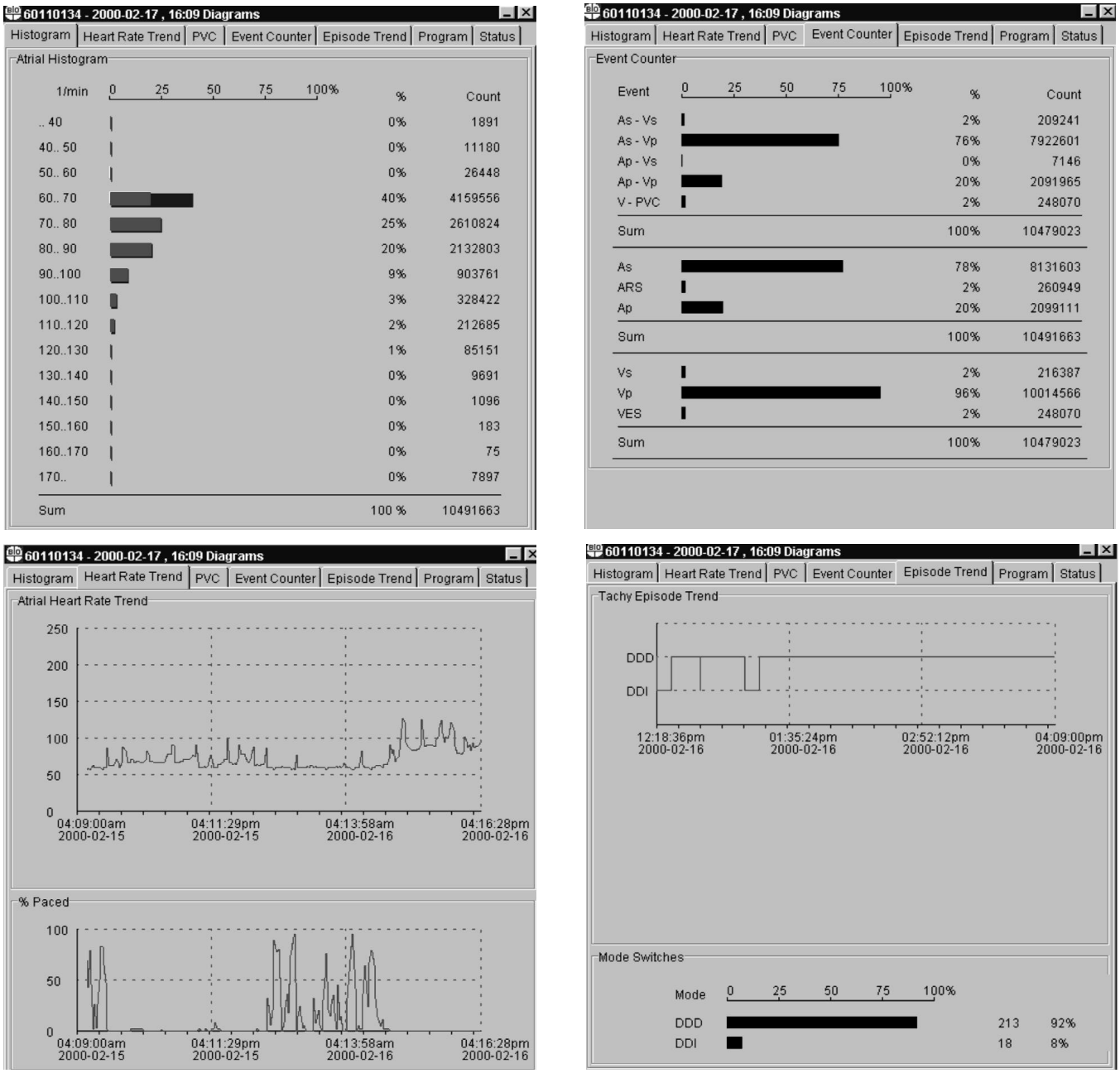
Dual-chamber stimulation
Up to 20% Stimulation in both chambers.

High-Rate Phases
1 long phase(s) (> 1h) were sensed at above 90ppm.

High-Rate Peaks
There are 4rate peaks above 120 ppm.

Detected atrial events during the refractory period
Greater share of sensed atrial events during the refractory period (3%).

Figure 4a. (see figure 4b, c next page)



b (above), c (below)

	Dual chamber stimulation	High rate phases
Screen output (feature)	Up to 20 % stimulation in both chambers	1 long phase(s) (> 1 h) were sensed at above 90 bpm
Rule	More than 5 % stimulation in both chambers	Lasting phases (more than 1 h) with frequences above 90 bpm
Conclusion		Sensed sinus rate is very high
Rationale	As a rule, dual-chamber stimulation is only necessary with a double node disease: Since double node diseases are rare, dual-chamber stimulation may also indicate misprogramming.	As a rule, pacemaker patients do not exert themselves so long or so strenuously that their heart rates achieve very high values. The treating physician can determine in follow-ups whether there is an external reason for the unusual values.

Figure 4. Data obtained during the follow-up of patient # 06 displayed in three different types of windows: analysis window (a; see page before), graphic windows with different contents (b), and evaluation window (c).

Patient	Pacemaker	ECG	Analysis	Actions taken
1	Logos	AVB	Intrinsic AV-conduction after As more frequent than after Ap. Programmed AV-time is possibly too short. Up to 16 % Stimulation in both chambers.	AV delay prolonged Activated hysteresis
2	Logos	AVB	1 long phase(s) (> 1h) were sensed at above 90 ppm.	No action taken
3	Logos	AVB	Intrinsic AV-conduction after As more frequent than after Ap. Programmed AV-time is possibly too short.	AV delay prolonged
4	Logos	AVB + AF	1 long phase(s) (> 1h) were sensed at above 90 ppm. Very high rates: 90 % of all atrial events are above 120 ppm.	No action taken
5	Logos	AVB	2 long phase(s) (> 1h) were sensed at above 90 ppm.	No action taken
6	Logos	AVB	Up to 20 % Stimulation in both chambers. Intrinsic AV-conduction after As more frequent than after Ap. Programmed AV-time is possibly too short. 1 long phase(s) (> 1h) were sensed at above 90 ppm.	AV delay prolonged (Switch Mode already active)
7	Logos	AVB	No abnormalities have been found.	No action taken
8	Logos	AVB	Up to 22 % Stimulation in both chambers. 3 long phase(s) (> 1h) were sensed at above 90 ppm. Very high rates: 12 % of all atrial events are above 120 ppm. Greater share of sensed atrial events during the refractory period (5 %).	AV delay prolonged Switch Mode activated
9	Logos	AVB	Up to 24 % Stimulation in both chambers. Ventricular Stimulation Occurrence 85 %. Intrinsic AV-conduction after As more frequent than after Ap. Programmed AV-time is possibly too short.	No action taken
10	Logos	AVB	There are 1 rate peaks above 120 ppm. Greater share of sensed atrial events during the refractory period (3 %).	No action taken
11	Logos	AVB	Up to 17 % Stimulation in both chambers. Larger share of (assumed) VES (8 %) Greater share of sensed atrial events during the refractory period (9 %). Intrinsic AV-conduction after As more frequent than after Ap. Programmed AV-time is possibly too short.	Atrial refractory period reduced
12	Logos	AVB	3 long phase(s) (> 1h) were sensed at above 90 ppm. Greater share of sensed atrial events during the refractory period (2 %).	No action taken
13	Logos	AVB	Intrinsic AV-conduction after As more frequent than after Ap. Programmed AV-time is possibly too short.	AV delay prolonged
14	Logos	AVB	Up to 12 % Stimulation in both chambers. Intrinsic AV-conduction after As more frequent than after Ap. Programmed AV-time is possibly too short.	AV delay prolonged
15	Actros DR	SSS: brady-tachy	Occurrence of atrial stimulation at night (100 %) higher than during the day (100 %). Up to 100 % Stimulation in both chambers. Intrinsic AV-conduction after As more frequent than after Ap. Programmed AV-time is possibly too short.	AV delay prolonged
16	Logos	AVB	No abnormalities have been found.	No action taken
17	Actros DR	SSS	Up to 25 % Stimulation in both chambers. Intrinsic AV-conduction after As more frequent than after Ap. Programmed AV-time is possibly too short.	No action taken
18	Actros DR	SSS	Up to 51 % Stimulation in both chambers. Intrinsic AV-conduction after As more frequent than after Ap. Programmed AV-time is possibly too short.	AV delay prolonged

Table 1, part I. (see Table 1, part II next page.)

Patient	Pacemaker	ECG	Analysis	Actions taken
19	Actros DR	SSS	Occurrence of atrial stimulation at night (90 %) higher than during the day (90 %). Up to 71 % Stimulation in both chambers. Ventricular Stimulation Occurrence 76 %. Intrinsic AV-conduction after As more frequent than after Ap. Programmed AV-time is possibly too short.	Night program activated AV delay prolonged
20	Actros DR	SSS: brady-tachy	Occurrence of atrial stimulation at night (68 %) higher than during the day (10 %). Up to 22 % Stimulation in both chambers. 2 long phase(s) (> 1h) were sensed at above 90 ppm. The actual average rate (73 ppm) is significantly higher than the average frequency indicated by the sensor (65 ppm). Ventricular Stimulation Occurrence 24 %. Intrinsic AV-conduction after As more frequent than after Ap. Programmed AV-time is possibly too short..	Night program activated AV delay prolonged (Switch Mode already active)
21	Actros DR	SSS	Up to 43 % Stimulation in both chambers. Intrinsic AV-conduction after As more frequent than after Ap. Programmed AV-time is possibly too short.	No action taken
22	Actros	SSS	No abnormalities have been found.	No action taken
23	Actros DR	SSS: brady-tachy	Occurrence of atrial stimulation at night (97 %) higher than during the day (94 %). Up to 41 % Stimulation in both chambers. 2 long phase(s) (> 1h) were sensed at above 90 ppm. Very high rates: 7 % of all atrial events are above 120 ppm. There are 2 rate peaks above 120 ppm. Ventricular Stimulation Occurrence 41 %. Intrinsic AV-conduction after As more frequent than after Ap. Programmed AV-time is possibly too short.	Night program activated AV delay prolonged (Switch Mode already active)
24	Actros DR	SSS	No abnormalities have been found.	No action taken
25	Logos	AVB	Occurrence of atrial stimulation at night higher than during the day. Up to 71 % Stimulation in both chambers. Intrinsic AV-conduction after As more frequent than after Ap. Programmed AV-time is possibly too short.	Basic rate reduced to 60 ppm Hysteresis at -10 ppm AV delay prolonged
26	Actros DR	SSS	Up to 25 % Stimulation in both chambers. Intrinsic AV-conduction after As more frequent than after Ap. Programmed AV-time is possibly too short.	AV delay prolonged
27	Actros DR	SSS	No abnormalities have been found.	No action taken
28	Actros DR	SSS: brady-tachy + AVB	Up to 45 % Stimulation in both chambers. Intrinsic AV-conduction after As more frequent than after Ap. Programmed AV-time is possibly too short. Low rate variability	AV delay prolonged Rate responsive mode DDDR activated
29	Actros DR	SSS	Up to 15 % Stimulation in both chambers. Intrinsic AV-conduction after As more frequent than after Ap. Programmed AV-time is possibly too short.	No action taken
30	Logos	AVB	No abnormalities have been found.	No action taken

Table 1, part II. Follow-up data obtained using the Scholiast System. The automatically generated report includes patient number, pacemaker model, ECG indication for pacemaker implantation (AVB = atrioventricular block, SSS = sick sinus syndrome, AF = atrial fibrillation), findings of the automatic rule-based data-analysis, and the actions taken. Some rules were modified during the study. No concrete actions were taken in those patients in whom the settings were considered correct, regardless of the results of the automatic analysis (see Table 1, part I page before).

the patient. The main objective of this evaluation was to find the means of correcting non-physiologic pacemaker responses and, wherever possible, to promote the patient's spontaneous activity. From these preliminary results in the patient population being studied, it was possible to observe and correct non-optimal data, especially regarding the atrioventricular delay, the hysteresis option, and the rate-responsive sensor functions, which may have easily been overlooked in a routine, non-detailed pacemaker follow-up.

Conclusions

The information obtained from this preliminary version of the expert system appears very interesting and promising. The data stored by the pacemaker and transferred to the computer are particularly helpful for a clinical evaluation of the patients' status and of the functions of the pulse generators. In this version, the expert system, integrated in the CDM 3000 patient data system, already offers interesting possibilities and potential clinical benefits through:

- the full diagnostic capabilities provided by modern pacemakers, which can be utilized without additional effort;
- the detailed technical and medical expertise provided by a knowledge-based support to the physician;
- the possibility of early and precise detection of the progression of diseases and of other risk factors;
- the expected, long-term optimization of the therapy; and
- the resulting, overall improvement in the quality of follow-ups.

The system of rules was also implemented to improve the quality of the analysis. A complete estimation of the clinical benefit was neither expected nor possible at this stage. However, in the subsequent phase of the study, an evaluation regarding this aspect will also be expressed on the basis of the experience that has been gained. Besides being a means to assess therapeutic efficacy, this type of automated analysis could, prospectively, be a step toward a remote control system that is also useful for heart disease monitoring and prevention.

References

[1] Sack S, Malinowski K, Appl U, et al. Analyse von Arrhythmien und Schrittmacherfunktionen durch die automatische Interpretation von Schrittmacher-Diagnosefunktionen. Herzschrittmacher. 1996; 16 (Suppl 11): 103-114.

[2] Limousin M, Geroux L, Nitzsché R, et al. Value of automatic processing and reliability of stored data in an implanted pacemaker: Initial results in 59 patients. PACE. 1997; 20: 2893-2898.

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