Computer Aided, Patient-Oriented Programming of Implantable Cardioverter Defibrillators

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Summary

Present dual-chamber ICDs offer a large variety of therapeutic options for all kinds of brady- and tachyarrhythmias. This variety results in an enormous number of technical parameters that the clinical user has to program to tailor the ICD to each individual patient in a time consuming procedure. This article presents a tool for the automatic setting of a complete set of technical parameters to overcome the disadvantages of the conventional programming process. The tool uses expert systems technology to calculate from entered clinical data the appropriate technical parameter set. First investigations demonstrate that the time-consuming procedure could be reduced by about 60 % in combination with the safety that a complete parameter set is generated. Furthermore the input uses exclusively clinical terms reducing the learning curve for the user. In conclusion, expert systems are feasible for easier and faster device programming. Furthermore they may be the only solution to provide access to all therapy options of implantable devices, because the expert systems support the user during the complex programming procedures for these algorithms.

Key Words

Implantable cardioverter defibrillator, expert systems, programmer

Introduction

Modern dual-chamber implantable cardioverter defibrillators (ICDs) provide a large variety of therapy options for the treatment of atrial and ventricular tachyarrhythmias, including antitachycardia pacing, high frequency bursts, and shocks. In addition, the latest devices offer all options for bradyarrhythmia therapy along with biatrial and biventricular pacing [1]. Furthermore, detection schemes in the atrium and ventricle, as well as therapy documentation, can be selected individually in order to tailor the device to the specific needs of each patient. The possibility of customizing the device to the specific arrhythmias and cardiac history of each patient brings with it the extra effort exerted by the physician in selecting an appropriate parameter set consisting of hundreds of individual technical parameters. Therefore, in order to program the device appropriately, the physician must be an expert not only in the therapy of rhythm disorders but also in the specific device being programmed. This programming procedure is device-oriented since the physician has to translate the clinical therapy that the device should deliver into a technical parameter set.

The programming procedure is time consuming. First, in modern dual-chamber ICDs with atrial and ventricular therapies, there are up to 250 different technical parameters; there is, therefore, a risk that some parameters are accidentally not or wrongly adapted to the patients need [2]. Second, the name and meaning of a parameter may differ from device to device among the several companies that offer D-ICDs; therefore, the physician may misinterpret the meaning of the value and program the parameter incorrectly. In addition, there is a complex

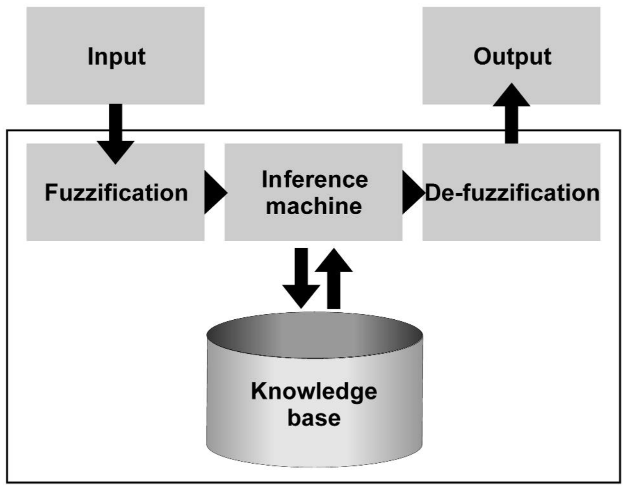


Figure 1. The expert system consists of the knowledge base, in which the rules of the human experts are stored, and the inference engine, which interprets the data of the specific case according to the stored rules. The input is first fuzzified to translate the data from a human-readable form into computer readable input. Then the inference process generates the output data, which are subsequently re-translated into human-readable form, or, in the specific case of the automatic programming system, into the device-readable form.

interaction between technical parameters and the algorithms in the devices. Without continuous study, the normal user cannot develop a complete picture of these interactions and, therefore, some therapeutic options may not be activated even if the device provides them and even if they are clinically useful.

Since future implantable devices will offer even more therapeutic options by including enhanced multisite support or preventive pacing with rate stabilization algorithms, the gap between the functionality offered by the device and the functionality used by the clinician may become wider. This gap can only be closed with the help of expert systems, which support the user during the programming process by automatically generating an appropriate parameter set from the clinical data. This article presents a tool for the computer aided programming of ICDs to overcome the disadvantages of the present programming procedure. The goal of the programming assisting system is to provide the physician with a patient-oriented programming device that prompts the clinician specify the patient's arrhythmias and symptoms, together with the general disease and functional states and relevant medication. From this information, the programming assisting system generates the appropriate parameter set. This provides a completely new way of programming implantable devices. The benefits for the clinical user are as follows:

- User-friendly ("language" of device programming is the language of the clinician).
- Faster programming (less and easier input is necessary).
- Better therapy control (appropriateness of the parameter set is cross-checked).

First, this article describes expert systems in general. Then, the programming assisting system for the Tachos DR dual-chamber ICD (Biotronik, Germany) is presented. The article concludes with the first results regarding the potential benefit of this system in clinical practice.

General Expert Systems

An expert system is an advanced computer program (i.e., instruction set) that mimics the knowledge and reasoning capabilities of an expert in a particular discipline [3]. Its designers strive to reproduce the expertise of one or several human specialists to create a tool that can be used to solve difficult problems. Among the different approaches like neuronal networks or object based systems a rule based expert system is especially suited for computer assisted programming of ICDs. This special form of expert system combines facts entered by the clinical user with separately stored rules that state relations between the facts to achieve a crude representation of reasoning analogous to artificial intelligence. In contrast to conventional computer programs a rule based expert system consists of two main components: the knowledge base, which contains the rules according to which the data is manipulated, and the inference engine, which interprets and evaluates the rules in the knowledge base. The knowledge base is generated from the knowledge of human experts; in the case of the programming assisting system, these experts are clinicians with expertise in the programming of ICDs as well as device developers. The major components of the expert system are described in Figure 1.

Especially in medicine specific data often cannot be represented by a precise number like the measured value of the ejection fraction or the age. Instead the clinician has to use less precise descriptions like "rare", "often" or "very often", e.g., for the number ventricular extrasystoles. To account for this fuzziness in the

Rule: Determine ventricular 1st shock energy

IF DFT tested THEN

SET 1st shock energy to the maximum of DFT limit + 10 J and 2 * DFT limit

OTHERWISE

SET 1st shock energy to 28 J

Rule: Determine ventricular 2nd shock energy

IF 1st shock energy < 25 J THEN

SET 2nd shock energy to 25 J

OTHERWISE

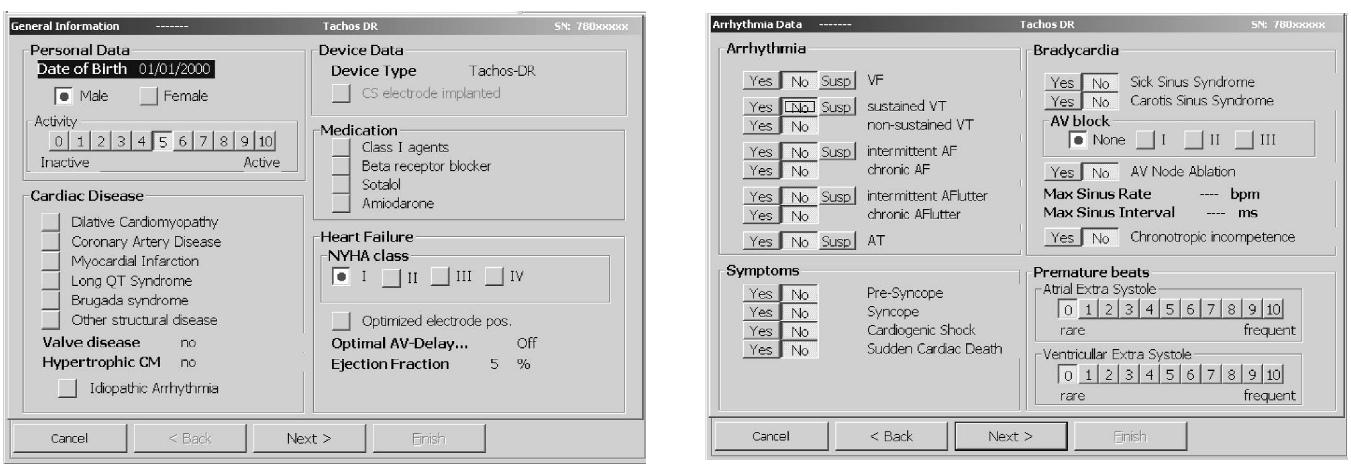
SET 2nd shock energy to 30 J

Figure 2. Example of rules implemented in the knowledge base. Based on the input parameters "DFT tested", "DFT limit", "myocardial infarction" the technical parameter of the first shock energy is calculated. In this example study results which describe the safety margin for programming the defibrillation energy based on the measured defibrillation threshold (DFT) are used in combination with the clinical experience of the experts [10, 11]. This example also demonstrates that the knowledge base has alternative rules if any of the tests is not performed.

data many expert systems make use of "soft" kind of logic, the fuzzy logic [4-5]. The input is translated during the fuzzification process from the human-readable form into a number of fuzzy sets, which the inference machine can then manipulate according to the rules. After the inference process, the data are de-fuzzified and translated into a human-readable form or, in case of the programming assisting system, into a device-readable form, i.e., the parameter set.

Programming Assisting System

The programming assisting system is based on the design of rule based expert systems as described in Figure 1. The knowledge base consists of rules, which describe how to calculate the technical parameters from the clinical input data. These rules, which were created during the knowledge acquisition process, represent the knowledge of clinical experts, who have long expertise in programming implantable devices, especially ICDs, in combination with the results of studies [6-8,10-11] and general guidelines [9]. In addition the knowledge of the device developers on device specific optimization possibilities is included as well. An example of rules for setting the defibrillation energy is shown in Figure 2. In the programming assisting system the physician enters the dynamic, patient specific input data during the device implantation. The data includes general data like patient age and medication, history of cardiac events especially of arrhythmias, functional data like activity level and NYHA class and measured data like pacing and defibrillation threshold. Figure 3 shows two of the input screens. The expert system calculates a complete set of technical parameters from the case-specific data according to the rules stored in the knowledge base. The expert system then supports the physician by allowing evaluation of the output. The system provides relevant information and reasoning about the calculation of the values. Figure 4 shows an example of the explanations given by this decision support system. After the examination



a b

Figure 3. Input screens for the automatic programming system. a) General patient data are requested. b) Data about tachy- and bradyarrhythmias and their hemodynamic impact are collected.

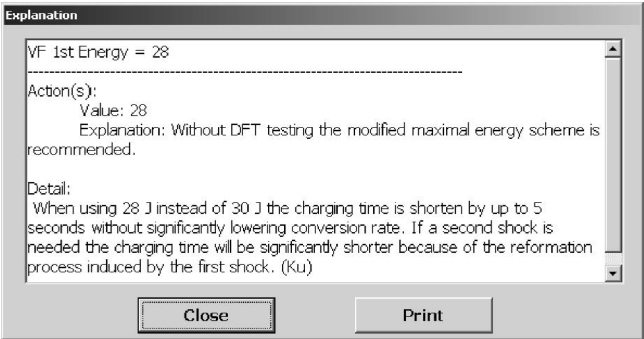


Figure 4. Example of an explanation for setting a parameter (1st shock energy) to a specific value of 28 J. This feature facilitates the evaluation of the generated parameter set and supports the clinical user.

of the generated parameter set by the physician, the final ICD program is transferred to the device.

Results

The user of the dual chamber ICD Tachos DR, for which the programming assisting system is designed, has access to 233 technical parameters to adapt the system to the specific needs of a patient. The present implementation of the knowledge base has the ability to include up to 120 clinical input parameters to calculate a complete parameter set for the Tachos DR. Many of these parameters depend on the presence of certain patient conditions. The programming assisting system suppresses for example questions on ventricular tachycardia cycle length, tolerance and symptoms if the physician specifies that the patient does not suffer from his kind of tachycardia. This reduces the average necessary input to less than 50 parameters for each patient. 12 of these parameters, like age or ejection fraction are already part of the patient data which is usually stored within the ICD and do not have to be reentered by the physician. In addition some of the input parameter are measured via the device like sensing and pacing thresholds and need not to be entered manually. Which leaves less than 25 new input parameter the physician usually has to enter into the system. The time for crosschecking the calculated parameter set is comparable to the final check of the parameter set, the clinical user has to perform after the conventional programming. This results in a reduction of the whole time consuming programming effort by at least 60 %.

All of the required input data uses clinical language and common technical terms. Therefore the need for the clinical user to learn a specific vocabulary or specific meanings of technical parameters is minimized.

Discussion

Present dual-chamber ICDs offer a large variety of therapeutic options for all kinds of brady- and tachyarrhythmias. This variety of options results in an enormous number of technical parameters that the clinical user has to program to tailor the ICD to each individual patient. The present programming procedure is time consuming due to the number of parameters and is a potential source of errors, since parameters could be accidentally forgotten or even set incorrectly. This article has presented a tool for the assisted patient-oriented setting of a complete set of technical parameters to overcome the disadvantages of the conventional programming procedure.

The present implementation of the programming assisting system already demonstrates that the time-consuming procedure could be reduced by about 60 %. In addition, the system ensures that a complete parameter set is generated, reducing the risk of accidentally forgotten parameters. Furthermore the required input uses exclusively clinical terms to reduce the learning curve for the clinical user. Nevertheless, a clinical study must demonstrate the safety and efficacy of the system in clinical use.

The programming assisting system presented here, in combination with automatic algorithms for setting parameters like the ventricular pacing amplitude [12], can remarkably reduce the effort required in the programming and follow-up of implantable devices. If, in addition, the input data are transmitted from the electronic patient folder in the clinical information system to the automatic programming device via currently available network technologies, an appropriate ICD parameter set can be generated without any additional effort.

In conclusion, expert systems that help the clinical user during the decision-making processes at implant and follow-up are feasible for easier and faster device programming. Furthermore they may be the only solution to provide all therapy options of implantable devices for broad clinical use, because the expert systems support the user during the complex programming procedures for these algorithms.

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