Clinical Experiences with a Subpectorally Implantable Cardioverter-Defibrillator Using a Single Lead System

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Summary

Due to continuously improved technologies, the present generation of implantable cardioverter-defibrillators (ICDs) guarantees a high degree of safety and efficacy for detecting and terminating ventricular tachyarrhythmias. The presented paper summarizes the clinical results obtained with 1058 single-chamber ICDs (PHYLAX 06, PHYLAX XM, BIOTRONIK) employing single-lead and active housing technology SPS and Kainox RV (single coil), SL-ICD and Kainox SL (double coil, BIOTRONIK). In all but 3 patients (> 99 %), reliable low-energy defibrillation was achieved using transvenous leads only. This has lead to the trend to replace DFT testing by a short function test during implantation in order to minimize the risks associated with repeated induction of fibrillation and extended anesthesia.

Key Words

implantable cardioverter-defibrillator, defibrillation threshold, transvenous leads, single-lead systems

Introduction

As ICD technology continuously improved, antitachycardic electrotherapy became a generally accepted tool for the treatment of tachyarrhythmias. Clinical studies have the superiority of the ICD in the prevention of sudden cardiac death as compared to antiarrhythmic drug therapy [1][2][3]. Crucial to the electrotherapy of tachyarrhythmias are reliable and early ventricular fibrillation (VF) detection as well as low DFTs. The importance of early arrhythmia detection is emphasized by the fact that prolonged fibrillation significantly reduces the probability of patient survival and increases the defibrillation threshold (DFT) [4]. In the absence of supraventricular arrhythmias, modern ventricular ICD systems are able to terminate most episodes of tachyarrhythmia. In this paper, the experience of clinics worldwide with a single-chamber ventricular ICD and its sensing and defibrillation performance is presented.

Methods

Patient Data

The ICDs PHYLAX 06 and PHYLAX XM have been implanted in 1058 patients (18.2 % females, 81.8 % males) with a mean age of 59 ± 14 years (ranging from 8 to 87 years). Diagnosed rhythms have comprised: sustained ventricular tachycardia (VT) in 64 %, VT and VF in 13 %, and exclusively VF in 23 % of the patients. As illustrated in Figure 1, the left ventricular ejection fraction was less than 30 % in 29 % of the patients, between 30 and 50 % in 50 %, and greater than 50 % in 20 % of the patients, with an overall mean value of 37.3 ± 15.4 %. Coronary artery disease was the primary cardiac disease in about 51 % of the patients, the second being cardiomyopathy with 22 %. Figure 2 shows the distribution of the primary cardiac diseases.

Device:

The PHYLAX 06 is a multiprogrammable single-chamber ICD with tiered therapy modules for the treat-

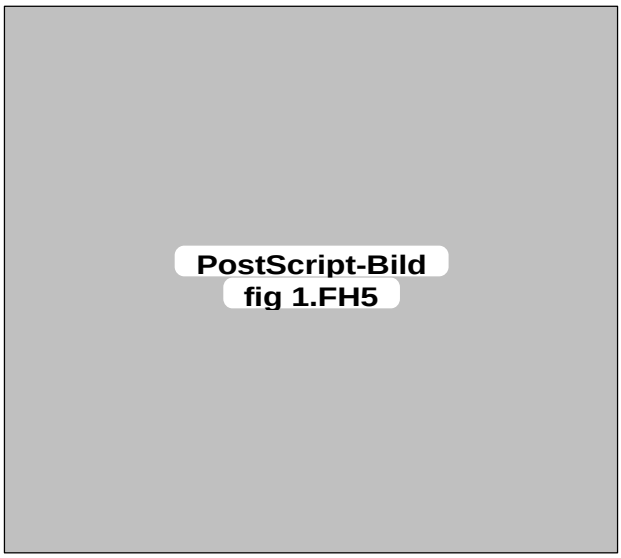

Figure 1. Distribution of ejection fraction.

ment of tachyarrhythmias. Its input stage is programmable and can thus be adjusted individually. Electrodes are fractal coated for enhanced sensing and defibrillation performance.

The device provides a modular therapy concept offering 1 VF and 4 VT detection zones with freely programmable detection criteria. It provides real-time IEGM Holter recording for 4 min and extended episode documentation. Besides antitachycardic functions, backup bradycardia pacing is available in the VVI mode. The PHYLAX XM offers addionally to these functions extended Holter memory capacities enabling the device to store up to 16 min of real time IEGM and 18000 RR intervals with a resolution of 4 ms.

Figure 2. Distribution of primary cardiac diseases.

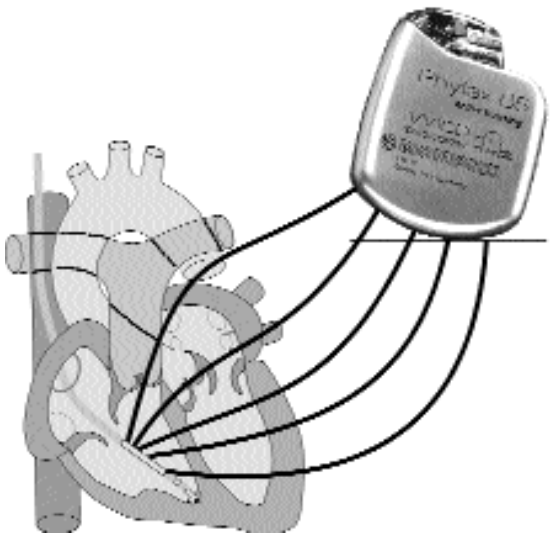

Figure 3. In Configuration 1, the shocks are released from the right ventricular shock coil to the active housing of the device.

Electrode configurations:

All implanted leads were transvenous single or dual coil lead systems. Whenever possible, the devices were implanted at a right pectoral site in order to profit from the optimized field geometry of the active housing technology (92 % of implanted PHYLAX 06 and PHYLAX XM). Three electrode configurations were used:

1. Right ventricular shock coil (SPS, KAINOX RV, BIOTRONIK) versus active housing, the standard application (Figure 3). Applied in 517 patients (76 %).
2. Right ventricular and vena cava shock coils on a single lead (SL-ICD, Kainox SL, BIOTRONIK) with the resulting field configuration of ventricular shock coil versus vena cava shock coil and active housing jointly. Applied in 70 patients (11 %).
3. Non-active housing configurations with the single lead system (SL-ICD, KAINOX SL, BIOTRONIK). Right ventricular shock coil versus the superior vena cava shock coil. Applied in 47 patients (7 %).

Another 6 % were ICD replacements with other leads in active housing configurations. Overall, only 3 pa-

pacing threshold	0.81±0.6 V
signal amplitude	14.3±6.7mV
pacing impedance	507±108 Ω
shock impedance	61.1±13.4 Ω

Table 1. Lead performance data from intraoperative measurements.

tients (less than 1 %) required an additional patch electrode to provide sufficient defibrillation energies.

Intraoperative measurements

During implantation, efficacy of antitachycardia and antibradycardia therapy were verified. Measurements included determination of R-wave amplitude, pacing threshold, pacing impedance, and shock impedance. Three different methods were used for verification of shock efficacy:

1. True DFT: A step-down test is continued until the first ineffective shock is observed. Then the shock energy is increased again. The energy of the first effective shock is defined the true DFT.
2. Reduced Step-Down Test: The step-down test is interrupted before an ineffective shock occurs.
3. Device Based Function-Test: One or two shocks are delivered with no more than 20 J. If no failure is observed, testing is finished.

All intraoperative pacing/sensing and defibrillation parameters were determined using the TMS 1000 system which combines the functionality of a programmer with that of an external shock/pacing threshold analyzer in a single device.

Results

Table 1 summarizes the results of intraoperative measurements. The low pacing thresholds of 0.81 ± 0.6 V and high signal amplitudes of 14.3 ± 6.7 mV document the high performance of fractal coated sensing/pacing electrodes. The average pacing impedance was 507 ± 108 W.

Each of the three methods for verification of shock efficacy was applied in about one third of the patient population respectively (cf. Figure 4). Evaluation of the intraoperative data revealed a clearly visible tendency among the participating centers to reduce the number of shocks applied: Mean true DFT was 12.95 ± 5.59 J whereas the endpoint of the reduced

Figure 4. Percent distribution of DFT test protocols: device-based function test, true DFT, and reduced step-down test.

step-down test was 9.48 ± 3.54 J. The only logical explanation to this phenomenon is, that there was a tendency to determine the true DFT only in those patients, where an ineffective shock was observed at an unexpected high energy. In this case, there was no alternative to confirming the efficacy of the shock therapy using an increased energy. Therefore, the above DFT values are expected to be heavily biased towards high energy levels.

In implantations with device-based function tests, sedation was used instead of general anesthesia during shock delivery. The number of shock deliveries, of course, was distinctly lower as compared to DFT tests (cf. figure 5). Both points reduce the intraoperative risk as well as the duration of the implantation procedure. Repeated fibrillation implies a series of ischemic events that contribute to the deterioration of the state of an already damaged heart.

Follow-up data document that all spontaneous epi-

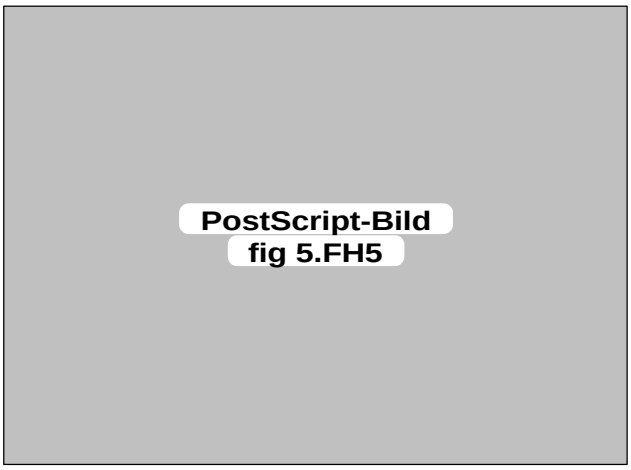

Figure 5 Average number of test shocks applied for each test protocol.

sodes of VF were terminated successfully. No arrhythmic deaths have been observed. The stored, episode data indicate that 55 % of all episodes were treated successfully with the first attempt of antitachycardia pacing (ATP). Usually, up to four ATP attempts are programmed in each class of VT. The high percentage of successful ATPs is attributed to the wide programmability of ATP sequences. This flexibility allows ATP therapy to be adjusted to the patients' specific needs as determined by the results of the electrophysiologic investigation.

Discussion

Clinical experiences with 1058 implantations worldwide demonstrate the safety and efficacy of the investigated system, with regard to arrhythmia detection and termination. In more than 99 % of the cases, single transvenous lead systems provided reliable low energy defibrillation, i. e. in only 3 patients additional patch electrodes were necessary. However, this proven shock efficacy has not led to a reduction of programmed energies, but rather initiated the tendency to refrain from determining the true DFT. For sure, this approach reduces the intraoperative risk associated with repeated fibrillation episodes and general anesthesia as required for DFT testing. Besides, it may reduce the time needed for the implantation procedure down to half an hour. The other side of the coin consists in accepting the deleterious effect of high shock energies in the long run. The observation of DFTs below 5 J in 10 % of the patients shows, that programmed energies of 15 or 20 J are often inadequate. The concerned patients would profit distinctly from the enormous progress that has been achieved in reducing the DFT by new technologies during the last decade. One approach in this direction was the introduction of multiphasic shocks [5]. Supplying mono-, bi-, tri-, and tetraphasic shocks, modern ICDs support pulse shape oriented DFT optimization. As far as the field distribution is concerned, the accessibility of the subpectoral implantation site in combination with active housing technology enabled an optimized field geometry. Reduction of the electric losses at the interface was attempted by a fractal Iridium coating of the electrode surface[6]. The combination of these technologies in the investigated device enabled application of very low defibrillation energies in a subgroup of patients. Thus, we feel the advantages of low DFTs still require a thorough discussion of the pros and cons of DFT testing that is not yet finished. The goal must be to improve the sensitivity and specificity of clinical criteria for the identification of low DFT patients prior to testing. Thus the requirements of low DFTs and efficient intraoperative testing could both be met in order to improve patient care.

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