Safety and Efficacy of Low Defibrillation Energies with Single Transvenous Leads — Clinical Experiences

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Summary

Due to improved technologies implantable Cardioverter-Defibrillators (ICDs) today provide a high degree of safety and efficacy for detection and termination of tachyarrhythmias. In the framework of the presented study 38 single chamber ICDs (Phylax 06, Biotronik) have been implanted in South America up to now. The clinical data are presented in comparison with the statistics of presently 516 implantations worldwide. While Chagas with 24 % is the most important primary cardiac disease in South America, worldwide statistics give coronary artery disease as the largest fraction with 55 %. Combining electrodes for sensing, pacing and shock delivery, single transvenous lead systems show an average DFT of 9.49 ± 5.1 J from worldwide implantation data. For more than 99 % of all patients these single transvenous lead systems reliably provide defibrillation with low energies, thus facilitating to replace extensive DFT testings by short function tests during implantation. Supporting function tests by external devices made it possible to reduce the average implantation time to less than 1 hour, approaching the regime of a pacemaker implantation.

Key Words

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

Introduction

As ICD technology continuously improved antitachycardiac electrotherapy became a generally accepted tool for the treatment of tachyarrhythmias. Clinical studies seem to prove a higher efficiency for the prevention of sudden cardiac death than antiarrhythmic drug therapy[1,2,3]. Important aspects for the electrotherapy of tachyarrhythmias are reliable and early VF detection as well as low defibrillation thresholds (DFTs). This is established by the fact that prolonged fibrillation distinctly enhances the DFT and significantly reduces the probability of patient survival[4]. In the absence of supraventricular arrhythmias ventricular-only ICD systems nowadays are able to terminate most episodes of tachyarrhythmia. In this work clinical experience on a single chamber ICD with the first 38 implantations in South America is presented regarding sensing and defibrillation performance. These data are compared with the clinical data on 516 implantations worldwide up to now.

Methods

In South America the Phylax 06 (Biotronik) has been implanted in 38 patients (30 % females, 70 % males) up to now with an average age of 59.3 ± 15.7 years

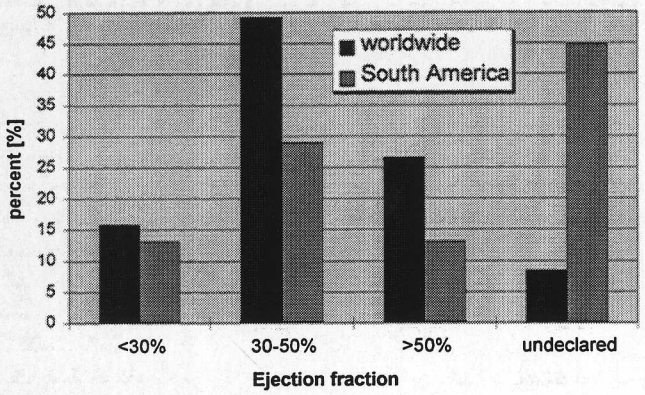

Figure 1. *Distribution of ejection fraction from all implantations worldwide.*

(range: 9 - 79 years). The left ventricular ejection fraction was less than 30 % in 23.8 % of the patients, between 30 and 50 % in 52.4 % of the patients and greater than 50 % in 23.8 % of the patients (see figure 1). Most frequent primary cardiac diseases were chagas with 24 %, and coronary artery disease, cardiomyopathy (dilatative / congestive) and abnormal automaticity with 13 % of the patients, respectively (figure 2).

Worldwide the Phylax 06 has been implanted in 516 patients up to now (20.7 % females, 79.3 % males) with a mean age of 58.9 ± 14.1 years (range: 8 - 85 years). Diagnosed rhythms have been sustained VT in 68 %, VT & VF in 10 % and exclusively VF in 22 % of the patients. As shown in figure 1, the left ventricular ejection fraction was less than 30 % in 17.3 % of the patients, between 30 and 50 % in 53.7 % of the patients and greater than 50 % in 29 % of the patients. Coronary artery disease was the primary cardiac disease in more than 55 % of the patients, followed by cardiomyopathy (dilatative / congestive) in about 19 % of the patients. Figure 2 shows the distribution of primary cardiac diseases worldwide in comparison with the patient data from South America. Patients in South America exhibit a significantly different distribution of primary cardiac diseases.

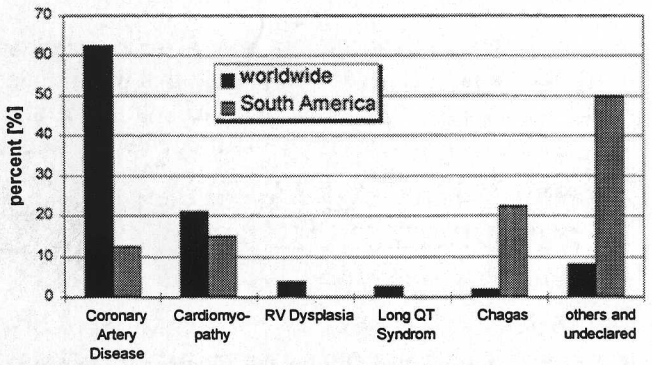

Figure 2. *Distribution of primary cardiac diseases: comparison of the worldwide statistic with the data from South America.*

Device:

The Phylax 06 is a multiprogrammable ICD with tiered therapy schemes for the treatment of tachyarrhythmias. Its input stage is programmable and thus can be adjusted to the patients individual needs. Electrodes are fractally coated to enhance sensing and detection performance.

The device provides a modular therapy concept offering one VF and four VT detection zones with free programmable detection criteria. It provides real time IEGM holter recording for 4 minutes and extended episode documentation. Besides antitachycardiac functions backup bradycardia pacing in the VVI-mode is available.

There are several factors which contribute to low defibrillation thresholds: First, the DFT may strongly depend on the shock morphology applied[5]. Therefore, besides monophasic shocks the investigated device also provides bi-, tri- and tetra-phasic shock morphologies, which are free programmable over a wide range. Second, the Phylax 06 is subpectorally implantable and therefore facilitates an optimized field configuration in combination with active housing technology. Third, shock coils are coated with a thin film of fractally structured iridium to reduce the shock energy unnecessarily dissipated at the interface to the blood[6], thus optimizing electrical field strenght.

Electrode configurations:

All implanted leads have been single transvenous lead systems. In order to make use of optimized field configurations during shock delivery most of the devices have been implanted with active housing technology (worldwide: 92 %, South America: 92 %). Three electrode configurations have been used for implantation:

1. Right ventricular shock coil (SPS, Biotronik) versus active housing. This configuration was used in 417 patients worldwide (81 %) and with 26 patients in South America (68 %), and is shown in figure 3.
2. Right ventricular and vena cava shock coils in single lead configuration (SL-ICD, Biotronik) with the resulting field configuration of ventricular shock coil versus vena cava shock coil and active housing. This configuration was used in 58 patients (11 %) worldwide and with 8 patients (21 %) in South America.

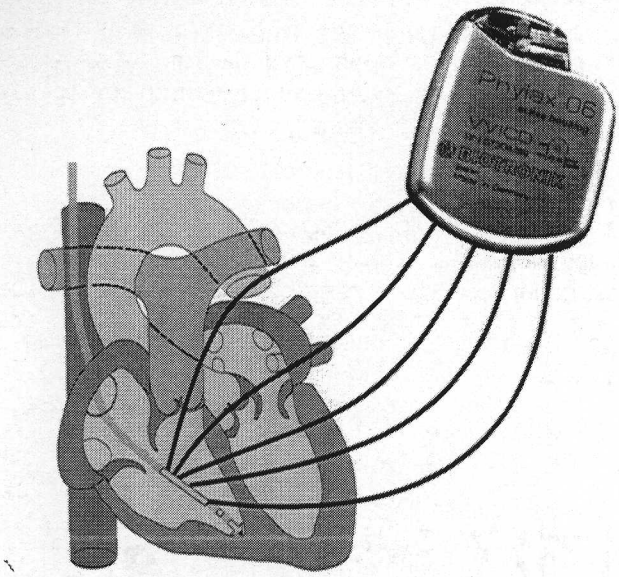

Figure 3. With configuration 1 the shocks are released between the right ventricular shock coil and the active housing of the device.

3. Non-active housing configurations which use the single lead system SL-ICD (Biotronik) with the right ventricular shock coil versus the superior vena cava shock coil (17 patients (3 %) worldwide, 3 patients (8 %) in South America).

Overall, only 3 patients (less than 1 %) an additional patch electrode needed to be applied in order to provide low defibrillation energies.

Results

The results of the intraoperative measurements are summarized in table 1 as a comparison of worldwide statistics and data from implantations at South America. Low pacing thresholds of about 0.9 V and signal amplitudes as high as 14 mV document the high performance of fractally coated sensing/pacing electrodes. Averaged pacing impedances have been about 470 Ω.

	Worldwide	South America
pacing threshold	0.89 ± 0.5 V	0.87 ± 0.56 V
range	0.3 .. 3.4 V	0.3 3 V
signal amplitude	13.8 ± 6.4 mV	14.2 ± 7.9 mV
range	4.5 .. 44.7 mV	5.3 .. 44.7 mV
pacing impedance	471 ± 96 Ω	493 ± 110 Ω
shock impedance	62.2 ± 13.5 Ω	60 ± 11 Ω

Table 1. Data from intraoperative measurements.

Figure 4 gives the worldwide distribution of DFTs from intraoperative testings. The maximum of the distribution is located between 9 and 11 Joules with about 63 % of all DFTs being lower than 11 Joules and 87 % smaller than 15 Joules. Low shock energies for successful defibrillation document the high reliability of the ICD system in terminating ventricular fibrillation. The high efficacy of configurations with transvenous leads and active housing technology prepared the way for a significant reduction of extensive DFT testings during implantation. With DFTs being low enough in most cases DFT statistics and extensive DFT testing lost relevance and patients are not tested until the true DFT is determined. On the one hand this causes the statistics to describe some kind of worst case evaluation, and on the other hand differences between various single transvenous lead systems vanish.

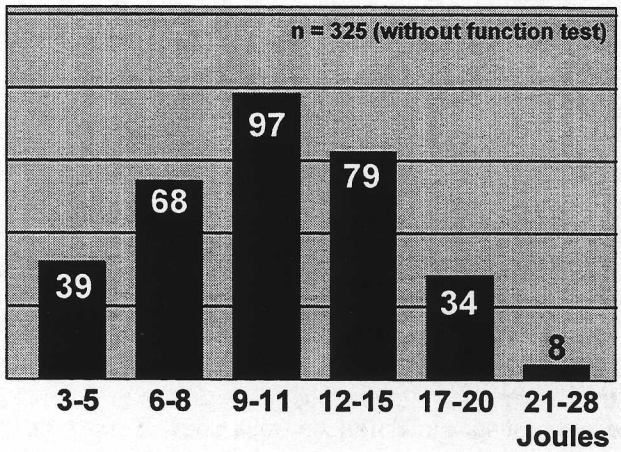

Figure 4. Distribution of DFTs taken from all implantations worldwide. Note, that the results of function tests, which attain a fraction of about 37 %, are not included.

In South America intraoperative testings on 74 % of patients have been stopped with successful defibrillation energies up to 15 Joules. Extensive testings on 5 patients reveal true DFTs of 4, 5, 5, 5, and 6 Joules. In comparison, worldwide statistics document an average true DFT of 13.0 ± 5.1 Joules.

Nowadays many implantations (about 37 %, see figure 4) are performed using a short function test which consists of one or two defibrillation shocks with 15 or 20 Joules. If this function test is successful, no further

testings are performed in order to reduce the patients load and risk during implantation. Accomplishing a function test comes along with not fully narcotizing the patient, but applying local anaesthesia during implantation, as known from pacemaker implantation. Only for the short time period of the function test patients get sedated. The PHYLAX 06 external equipment for implantation gets minimized by providing so-called device based testing. With the programmer unit (TMS 1000, Biotronik) as the only external device needed, implantation procedure gets further simplified. All these factors contribute to a distinct reduction of implantation duration. As a result it was possible to reduce implantation time from about 2 hours (worldwide average: 116 ± 54 min) to less than one hour, approaching the regime of pacemaker implantations.

Follow-up data document that all spontaneous episodes of ventricular fibrillation have been terminated successfully. There have been no deaths for rhythmological reasons. The extended episode storage gives a fraction of 55 % of successful first attacks of antitachycardia pacing with usually up to four ATP attempts being programmed in the VT-class. The high fraction of successful ATPs relates to ATP sequences being programmable over a wide range, thus enabling to adjust ATP therapy to the patients specific needs according to the results of the electrophysiological examination.

Discussion

Patient statistics in South America show distinct differences for the distribution of primary cardiac diseases in comparison to worldwide data. However, a likewise efficious therapy of patients in South America was observed. Clinical experiences both with more than 500 implantations worldwide as well as 38 implantations in South America demonstrate the saftey and efficacy of the investigated device regarding arrhythmia detection and termination in combination with single transvenous leads. In more than 99 % single transvenous lead systems provide reliable low energy defibrillation. Low DFTs pioneered a significant reduction of extensive DFT testing during implantation. In combination with single lead systems and improved external devices implantation procedure can be markedly shortened approaching the time frame of pacemaker implantations.

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