Analysis of Prolonged Procedure Time for the Implantation of Transvenous Single-Chamber Defibrillators

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Summary

The aim of our study was to analyze the frequency and rationale for performing a prolonged implantation procedure in patients with a single-chamber implantable cardioverter defibrillator (ICD), defined as a procedure > 90 min between skin incision and skin closure. The study included 112 patients who received the same single-chamber ICD with active housing and the same single-coil defibrillation lead for their first pectoral implantation. Patients whose procedure was less than or greater than 90 min were compared with each other. Total procedure time was separately analyzed as the time from skin incision to the insertion of the defibrillation lead, to the end of pacing measurements, and until skin closure. In total, 19 (18%) patients had a prolonged (123 ± 43 min), and 89 (82%) had a shorter procedure time (58 ± 18 min). The clinical data for the two groups were similarly distributed. The main difference was due to the time required for lead placement (shorter: 18 ± 12 min; prolonged: 46 ± 32 min; $p < 0.05$). The number of ventricular fibrillation conversions in patients with a prolonged duration (2.7 ± 1.3 tests) was less frequent than in patients with a shorter duration (3.4 ± 1.3 tests; $p < 0.05$). There was no significance in the number of step-down defibrillation threshold tests (shorter: 20 of 89 patients; prolonged: one of 19 patients) and lead dislocations occurred within 3 months after implantation (shorter: three of 89 patients; prolonged: two of 19 patients). Four patients received an additional superior vena cava lead, whereby three had a procedure time ≤ 90 min (74 ± 13 min), and one had a prolonged time of 150 min. In our study, patients with a procedure time > 90 min could not be determined in advance based on their clinical data. The main reason for the prolonged time was the difficulty in implanting the defibrillation lead, and not the increased defibrillation threshold.

Key Words

Implantable cardioverter defibrillator (ICD), transvenous defibrillation lead, ICD implantation, lead body, procedure time

Introduction

Implantable cardioverter defibrillators (ICD) have become a very efficient mechanism for preventing sudden cardiac death in patients who have been successfully resuscitated [1]. Transvenous leads in combination with pectoral implantation of an ICD with active housing have replaced the thoracotomy approach and the use of epicardial leads. This simplified approach has shortened the procedure time, especially when conscious sedation was used [2-5]. An ICD implantation performed in less time is beneficial to both the patient and the implanting physician. These technical improvements reduce the costs for ICD implantation [6-11], and a shorter procedure time can also lower the facility costs. In this way, a more or less predictable procedure time can become an indicator for quality control. The reasons for a shorter procedure time in patients with transvenous pectorally implanted ICDs have not yet been assessed. There are two potential causes for a prolonged procedure: the time needed to determine a stable lead position in the right ventricle, and an increased defibrillation threshold so that more ventricular fibrillation (VF) conversion tests and the implantation of addi-

tional defibrillation leads become necessary [12]. The aim of this study was to analyze the frequency of prolonged procedures and their necessity in patients with a single-coil defibrillation lead and a single-chamber active-can ICD.

Materials and Methods

Patients

This prospective study included 112 patients from 20 European centers who received the same single-chamber ICD and single-coil defibrillation lead for their first implant. If the defibrillation threshold was > 20 J, the implantation of a second defibrillation lead in the superior vena cava (SVC) was recommended. Each patient gave their informed consent prior to the investigation.

ICD and Defibrillation Lead

Ten patients were implanted with the Phylax 06 ICD (69 cm^3 device volume, 109 g device weight), 76 were implanted with the Phylax XM (69 cm^3, 109 g), and 26 were implanted with the mycro Phylax (54 cm^3, 89 g) (all ICDs from Biotronik, Germany). The Kainox RV defibrillation lead (Biotronik) is a single defibrillation coil with a 3.0 cm^2 surface area and a true bipolar electrode with a 5 mm^2 surface tip area. The lead body has a 6.7 French diameter.

From the four patients who received an additional superior vena cava defibrillation lead, three were implanted with the Kainox VCS60 (Biotronik) and one with the Ventritex VCS03 (St. Jude Medical, USA).

Implantation Procedure

The submuscular pocket for the ICD was prepared by first making a skin incision, and then venous access was obtained. The defibrillation lead was placed in the bottom or apex of the right ventricle, and the position was confirmed radiologically. The pacing threshold, pacing impedance, and R wave amplitude were determined using the TMS 1000 (Biotronik) pacing system analyzer. The recommended settings were: R wave amplitude > 5 mV and pacing threshold < 1.0 V at a pulse width of 0.4 ms. Ventricular fibrillation conversion tests were performed using the TMS 1000 in 58 patients. In the remaining patients the defibrillation lead was connected to the device, and device-based testing of VF conversion was performed. It was the implanting physician's decision to either verify the termination of induced VF twice with sufficient converting energy (20 J stored), or to determine the defibrillation threshold with a step-down protocol (15, 10, 8, 5, 3 J). Then the tissue was approximated and the incision was closed. Follow-up measurements were performed at the time of hospital discharge and 3 months after implantation. At each follow-up, the diagnostic counters were interrogated and the pacing functions were determined.

Analysis

A prolonged implantation time was defined as a procedure > 90 min from skin incision to skin closure. The rationale for this decision was based on previous studies, where the mean procedure time was determined to be approximately 90 min [4,13]. Patients with implantation times ≤ 90 min and > 90 min were compared with respect to their clinical characteristics and specific implantation times. Thereby, "total procedure time" was defined as the time from skin incision until closure. This time was further divided into introduction, lead implantation, and closure times. "Introduction time" was defined as the time from skin incision to the insertion of the defibrillation lead into the vein. "Lead implantation time" was defined as the time from lead insertion into the vein until the conclusion of the electrical measurements using the TMS 1000 monitoring system. The "closure time" described the time until skin closure, which included the time for the VF conversion tests. It was the implanting physician's decision to perform either a complete defibrillation threshold test, or a device-based function test (with 15 – 20 J) on two occasions.

Statistics

Data are presented as a mean, with a standard deviation when appropriate. Statistical analyses were performed with the two-sided Mann-Whitney test, and with the exact Fisher test; p-values < 0.05 were considered statistically significant.

Results

Patients with a Single-coil Defibrillation Lead

From the 108 patients with a single-coil defibrillation lead, 19 (18%) had a prolonged and 89 (82%) had a shorter procedure time. The clinical data for the two groups is presented in Table 1. The mean defibrillation threshold in the 21 patients tested was 10.2 ± 3.9 J.

		Procedure duration ≤ 90-min	> 90-min	
	No. of patients	89	19	
	Age (years)	61 ±12	61 ±18	n.s.
	Male	76 (85%)	15 (79%)	n.s.
	LV ejection fraction (%)	38 ±16	39 ±15	n.s.
Underlying heart disease	Coronary heart disease	54 (61%)	16 (84%)	n.s.
	Dilated cardio-myopathy	2 (2%)	0 (0%)	n.s.
	Valvular heart disease	17 (19%)	1 (5%)	n.s.
	Primary electrical disease	11 (12%)	2 (11%)	n.s.
	Other cardiac disease	5 (6%)	0 (0%)	n.s.
Indication for ICD therapy	Ventricular fibrillation	40 (45%)	8 (42%)	n.s.
	Ventricular tachycardia	42 (52%)	11 (63%)	n.s.
	Prior myocardial infarction	7 (17%)	0 (21%)	n.s.
Implantation side	Left pectoral side	88 (99%)	18 (95%)	n.s.
	Right pectoral side	1 (1%)	1 (5%)	n.s.
Anesthesia	General anesthesia	71 (80%)	13 (68%)	n.s.
	Local anesthesia	18 (20%)	6 (32%)	n.s.
Implanted by	Surgeon	66 (74%)	15 (79%)	n.s.
	Cardiologist	23 (26%)	4 (21%)	n.s.
Implantation location	Catheter Laboratory	54 (61%)	9 (47%)	n.s.
	Operation room	35 (39%)	10 (53%)	n.s.
	No. of centers	19	11	n.s.

Table 1. Characteristics of the patient groups with procedure times ≤ 90 min and with procedure times > 90 min. n.s.= not significant

Implantation

The "total procedure time" was 123 ± 43 min in the prolonged, compared with 58 ± 18 min in the shorter group. This was primarily due to the lead placement time of 46 ± 32 min in the prolonged, versus 18 ± 12 min in the shorter group (Figure 1). The number of VF conversion tests were induced less frequently in the prolonged group compared with patients in the shorter group (2.7 ± 1.3 versus 3.4 ± 1.3; $p < 0.05$). Step-down defibrillation threshold tests were performed in one (5%) patient of the prolonged, and 20 (22%) patients in the shorter group (not significant). A VF conversion test with the lowest required defibrillation energy was performed in 18 patients (95%) in the prolonged, and in 69 patients (76%) in the shorter group (not significant). After induction, VF episodes were observed more often with respect to ventricular tachycardia (VT) episodes in the shorter than in the prolonged group (VF / VT = 302 / 6 versus 51 / 15; $p < 0.05$).

Follow-up

There were no fatalities, and no ICD infection was observed at the 3-month follow-up. There were three (3.4%) lead dislocations in the shorter group and two (10.5%) in the prolonged group (not significant). The electrical lead functions remained similar in the two groups (Table 2). Five (26%) patients in the prolonged group had 17 spontaneous episodes of VF and/or monomorphic VT; 21% of patients in the shorter group had 76 spontaneous episodes of VF and/or monomorphic VT. Four (24%) and 12 (16%) episodes in the prolonged and shorter group terminated spontaneously and the ICD successfully terminated the remaining 13 (76%) and 64 (84%) episodes, respectively. From a total of 12 false-positive episodes, five episodes occured in four patients from the shorter group, and seven episodes occured in two patients from the prolonged group.

Patients with an Additional Defibrillation Lead

A defibrillation threshold > 20 J was the indication for placement of an additional defibrillation lead (Kainox VCS60) in the SVC in three patients (57 ± 18 years; all male). The procedure time was < 90 min, with a mean procedure time of 74 ± 13 min. One patient (21 years; male) received an additional defibrillation lead (Ventritex VCS03) because two shocks induced a sustained VT. This patient's procedure time was 150 min. A VF conversion test with the

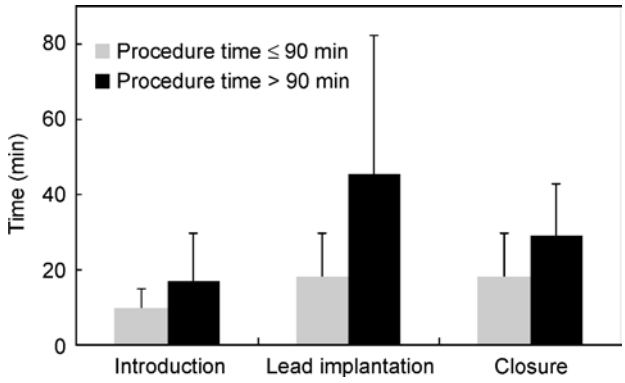

Figure 1. Comparison of the different implantation times in patients with procedure times ≤ 90 min and with procedure times > 90 min.

lowest required defibrillation energy was performed in all four patients. The number of induced VF episodes was 4.7 ± 1.2 in the shorter group and seven VF episodes in the prolonged group. All induced episodes in the four patients were VF. The lead became dislocated in one patient in the shorter group, and in the patient in the prolonged group.

		Procedure duration ≤ 90-min	> 90-min	
Implantation	R-wave amplitude (mV)	16.5 ±8.3	12.1 ±7.1	n.s.
	Pacing threshold (V)	0.6 ±0.2	0.5 ±0.2	n.s.
	Pacing impedance (Ω)	673 ±120	637 ±105	n.s.
Hospital predischarge	Pacing threshold (V)	1.2 ±1.0	1.4 ±1.1	n.s.
	Pacing impedance (Ω)	536 ±82	513 ± 53	n.s.
3-month follow-up	Pacing threshold (V)	1.4 ± 1.1	1.3 ± 0.6	n.s.
	Pacing impedance (Ω)	664 ± 128	630 ± 109	n.s.
6-month follow-up	Pacing threshold (V)	1.4 ± 0.9	1.2 ± 0.4	n.s.
	Pacing impedance (Ω)	650 ± 124	619 ± 100	n.s.

Table 2. Pacing and defibrillation characteristics of the patient groups with procedure times ≤ 90 min and with procedure times > 90 min. n.s. = not significant.

At the 3-month follow up there were seven spontaneous VF and/or monomorphic VT episodes in the three shorter group patients, and one episode in the prolonged group patient. Three episodes were spontaneously terminated, and the device successfully terminated four (57%) episodes. The episode of the patient in the prolonged group was false positive due to T wave oversensing; it was inappropriately treated with an ICD shock.

Discussion

Patients with a procedure time ≤ 90 min and > 90 min were compared with each other. The prolonged procedure duration contained 18% of the patients. These patients could not be identified in advance by their clinical findings. The main reason for the prolonged implantation time was related to the more difficult implantation of the defibrillation lead, and not due to a high defibrillation threshold as indicated by the number of VF inductions, or the need for an additional defibrillation lead. The study had included only patients with the same defibrillation lead and single-chamber defibrillators to exclude differences related to the different leads implanted. High defibrillation thresholds continue to be a relevant issue in ICD therapy as recent devices have a maximum output < 34 J in order to decrease their size [14]. The present findings indicated that a high defibrillation threshold rarely occurred with the studied device configuration, and can be easily overcome in the few cases with an additional defibrillation lead.

To our knowledge there are no investigations that have systematically analyzed implantation times. In our investigation the time to find a stable lead position determined the duration of the procedure in most patients. There are three variables interacting with each other: the type of lead, the patient's anatomy, and the implanting physician. All patients received the same type of defibrillation lead. The defibrillation lead itself seems to have little effect on the length of the procedure, as the procedure duration in recently published studies using other leads was not different [4,13].

The inter-individual variability in the patient's anatomy with respect to lead implantation is difficult to assess. As shown in the present analysis, the clinical data did not help us to identify in advance those patients undergoing a prolonged procedure. In addition, the two groups had a similar occurrence of spontaneous

episodes during follow-up. The third component is the experience and skill of the implanting physician. As shown in Table 2, surgeons and cardiologists had a similar performance when analyzed as a group, and at least one patient in the prolonged procedure group was observed in most centers. However, patients who had prolonged procedures often had three times as many lead dislocations compared with the shorter group. This could either be related to those patients with a more complex anatomy, or to a less experienced clinician, or to both.

An ICD implantation should above all be safe for the patient. Beyond that, it should be performed within the expected time schedule. This is in the interest of the patient and helps to control facility costs, which can ultimately effect quality control.

Participants

Principal Investigator: Andreas Schuchert, Hamburg (Germany); Deputy: Carlos Borasteros, Avila (Spain); Germany: Joachim Witte, Berlin; Alexander Schirdewan, Berlin; Ulrich Kreutzer, Cottbus; Michael Drexler, Wiesbaden; Thomas Meinertz, Hamburg; Hans-H. Minden, Bernau. France: Nicolas Sadoul, Nancy; Phillipe Chevalier, Lyon; Dominique Lamaison, Clermont-Ferrand; Michele Salvador-Mazenq, Toulouse; Patrick Blanc, Limoges; Belgium: Pedro Brugada, Aalst; Hungary: Bela Merkely, Budapest; Italy: Leandro Chiodi, Firenze; Spain: Nicolas Pachon, Oviedo; Amos Katz, Beer Sheva; Menashe Epstein, Rechovot; United Kingdom: Jaswinder Gill, London.

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