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ORIGINAL ARTICLE

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Reduction of defibrillation threshold and safety of usage of a new model of subcutaneous defibrillation lead

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Folia Medica Copernicana 2014;
Volume 2, Number 3, 84–92

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ISSN 2300–5432

ABSTRACT

This study was designed to evaluate the performance of a new single coil model of a subcutaneous defibrillation lead (Medtronic, 6996S) by assessing its capability to lower the defibrillation threshold. The 6996S lead is a permanent unipolar subcutaneous lead with a short (15 cm) defibrillation coil. Additionally, the safety of the lead and its chronic stability were evaluated.

The investigation was performed in patients who underwent implantation of an ICD system consisting of a single coil RV lead with a left sub-clavicular Active Can ICD. In these patients, the DFT was determined twice during the implantation procedure with a binary search protocol, once with an ICD system which included the 6996S lead (RV → Can + SQ), and once without the 6996S lead (RV → Can). The order in which the implanted system configurations were tested was randomised.

Between June 2004 and February 2006, 32 patients were enrolled into the study. Post-implantation follow-up was of at least three-month duration. The DFT test results of 31 patients have been analysed. The average DFT of (Can → RV) and (Can + 6996S → RV) were respectively 14.3 ± 9.9 J and 10.5 ± 6.2 J ($p = 0.007$). The addition of the 6996S lead with 15 cm coil reduced the average DFT by 27%, which is about 80% of the DFT reduction obtained with the 6996 lead with 25 cm coil. Adverse events, predominantly related to progression of heart failure, were observed in eight (26%) patients during the study and were related neither to the particular 6996S lead model, nor to the implant procedure.

The short-coil (6996S) SQ lead significantly reduced mean DFT. The implant procedure is safe, but the 6996S lead requires / warrants long-term surveillance / observation due to retraction of the tip of the lead, ranging from 1 to 4 cm, found in eight of 14 patients (57%) implanted with this lead model.

Key words: additional defibrillation lead, high defibrillation threshold, randomized study

Folia Medica Copernicana 2014; 2 (3): 84–92

Introduction

Patients at risk of sudden cardiac arrest should be secured with an implantable cardioverter-defibrillator (ICD) system. High voltage circuit of the ICD is the part of the device that is crucial in terms of saving life. Nowadays, ICD systems consist of two parts through which high energy is delivered to the heart: one of which is intracardiac — defibrillation-coil right ventricular lead, and the other one extracardiac — the active can of the device. The implantation procedure comprises an assessment of appropriate tachyarrhythmia detection capability of the system as well as the ability of the system to provide adequate defibrillation therapy — defibrillation threshold testing (DFT). The technical evolution of the ICD systems (e.g. 40 J devices) decreases the incidence of high DFT. Though, if present, resolving high-DFT issues can represent a very challenging task for implanting physicians. One of the most efficient ways in that situation is the implantation of an additional, subcutaneous lead, which decreases the assessed high defibrillation threshold. Subcutaneous patches

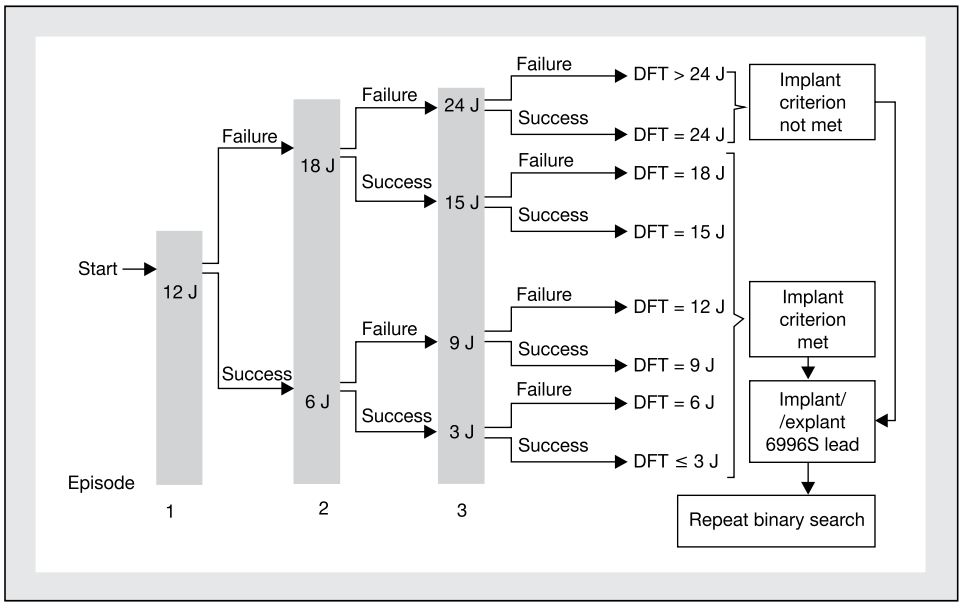

Figure 1. Binary search protocol

have been shown to be less effective and cause more complications than array or single coil electrodes [1–3].

Purpose of the study

This study was designed to evaluate the performance of a new model single coil subcutaneous defibrillation lead (Medtronic 6996S) by assessing its capability to lower the defibrillation threshold demonstrating a significant reduction of the mean DFT with the Can + 6996S → RV configuration compared to the mean DFT for the Can → RV standard configuration at implant. Additionally, the safety of lead implantation and chronic stability were evaluated.

Methods

The clinical investigation of the 6996S lead was a multi-centre, randomised, prospective, clinical research study. Between June 2004 and February 2006, five centres (one in Germany, four in Poland) enrolled 32 patients in the study. The 6996S lead is a permanent unipolar subcutaneous lead with a single defibrillation coil. It was designed to provide improved ease of use compared to the market-released model 6996 (Medtronic), while maintaining improved defibrillation characteristics. The lead comprises a DF-1 connector, a silicone lead body, a platinum-iridium coil electrode and a distal silicone tip. Its design is similar to the design of the 6996 lead model, with the main difference being the reduction in coil length from 25 cm to 15 cm.

The investigation was conducted in compliance with the study protocol, EN 540, the Declaration of Helsinki, and in accordance with institutional ethic board guidelines. An enrollment rate of approximately 60 patients was anticipated in order to provide at least 50 patients for complete analysis of the DFT data and 25 patients chronically implanted with the 6996S lead for a three month follow up. Patient enrollment was consecutive. An interim analysis was planned after 36 patients.

All patients were implanted with single RV-coil defibrillation leads (Medtronic Sprint 6943 or Sprint 6932). The ICD devices were Medtronic GEM III VR/DR or Medtronic Marquis VR / DR. DFT was determined twice at implant, according to the binary search protocol (Fig. 1). Two configurations labelled (A) and (B), respectively with (Can + 6996S → RV) and without (Can → RV) the 6996S lead, as an active part of the defibrillation system, were tested. The order of implantations of particular types of systems, as well as the DFT assessment sequence (A → B or B → A), were set in a randomised manner. With configuration A tested first, the 6996S lead was explanted after the DFT test to avoid its potential influence on the test with the B configuration. Hence, these patients did not have the 6996S lead chronically implanted and did not require post-implant follow-up, except for adverse events related to the insertion of the subcutaneous lead that occur due to the implant protocol. Patients in whom configuration A was tested secondly had the 6996S lead chronically implanted and had to be followed after one, three and six months thereafter, until the last patient in the study had completed the three-month follow-up. For the purpose of

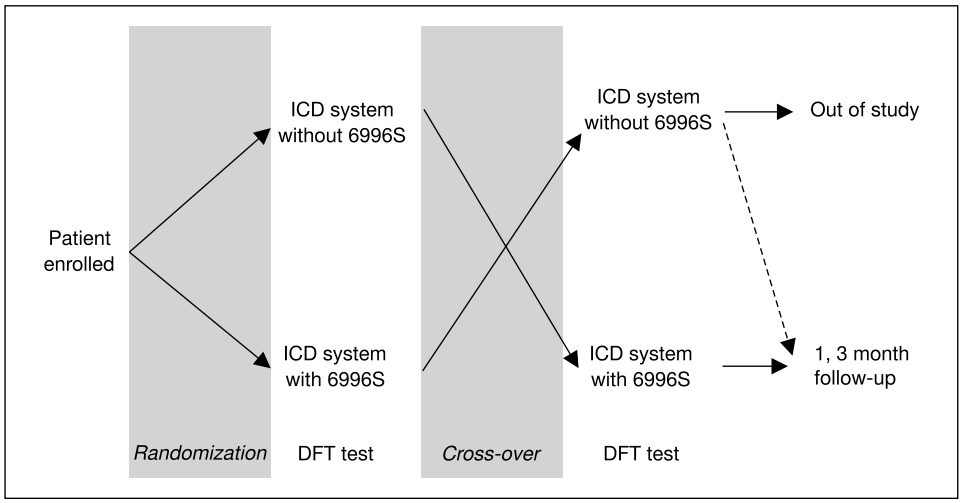

Figure 2. Model 6996S study design

the study, data collection was required only until the three-month follow-up visit to meet the study objectives. Any occurring adverse events and unscheduled follow-up visits mandating device interrogation, reprogramming or patient discontinuations in the study were documented as well (Fig. 2). In a patient who had been randomised to an arm of the study and not to receive the 6996S lead chronically but had a high DFT threshold or did not meet the implant criteria with the Can → RV lead configuration, the physician might have decided to reimplant the 6996S lead after the Can → RV lead system was tested. Once this was done, the patients had to be followed according to the protocol for at least three months. All adverse events were reported to the study sponsor (Medtronic Bakken Research Centre). The list of anticipated adverse events was divided into two categories: ICD implant-related, and subcutaneous lead-related.

Statistical analysis

Statistics for the categorical variables are reported as counts and percentages, and as mean values and standard deviation for continuous variables. To test for difference in distributions, we used the two-sided Fisher test for proportions (α = 0.05). For paired continuous data, we applied one-sided paired t-test (α = 0.025) after checking that relevant assumptions were met. For testing whether using amiodarone leads to a higher DFT, the non-parametric Wilcoxon two sample test (α = 0.05) was used, as the normality assumption for t-test was not met. The analysis was performed using Excel 7, with the exception of the statistical tests which were performed using the SAS 9.2 software.

Results

An interim analysis was planned after 36 patients had been enrolled in the study. However, due to an unexpectedly low enrollment rate, the interim analysis was performed prematurely after the inclusion of 32 patients. Having met the primary endpoint of the study, further enrollment was discontinued.

Patient demographics, indication for ICD implantation and cardiovascular history are shown in Table 1. Almost all patients in the study were male (31 male). In 69% of the cases, the aetiology of heart failure was ischaemic, with a mean left ventricular ejection fraction of 31.5 ± 10.6%. The patients' functional status as assessed according to NYHA classification was class I in 13% of cases, class II — 53%, class III — 31%, and class IV — 0%. Half of the examined patients were treated with amiodarone.

There was one case of failure of ventricular fibrillation induction, so the final analysis included only 31 patients.

Figure 3 shows anterior-posterior and lateral X-ray images of the intended lead positions in a patient from the 6996S study compared to parallel images from a 6996 study patient as a reference.

16 patients were randomised to have the 6996S lead-based configuration tested first, while in the remaining 15 participants it was tested second. In two patients without the 6996S lead, the necessary backup shocks required using 34 J and 35 J devices, while the other backup shocks were obtained at 30 J.

Five patients required deviations from the Binary Search Protocol, mainly due to the failure to defibrillate at high energy with the non-6996S lead configuration, making the execution of the protocol incomplete. In these cases, the lowest successful defibrillation energy of a test shock or backup shock was recorded as the DFT.

Table 1. Patient demographics, indication for ICD implantation, cardiovascular history of examined group of patients

Patient demographics	**(mean ± SD)**	**Number**
Patient gender: male		31/32 (97%)
Patient height	172.6 ± 7.5	32
Patient weight	76.2 ± 11.6	32
Patient age	59.5 ± 11.0	31
Indication for ICD implant		**Number**
Cardiac arrest		15/32 (47%)
LVEF < 30 at least 1 month prior MI		6/32 (19%)
Spontaneous recurrent, poorly tolerated, sustained VT		22/32 (69%)
Non sustained ventricular tachycardia		5/32 (16%)
Previous RV lead with a RV coil only and true bipolar sensing		4/32 (13%)
Cardiovascular history	**(mean ± SD)**	**Number**
Coronary artery disease		22/32 (69%)
Congestive heart failure		2/32 (6%)
Hypertension		9/32 (28%)
NYHA Functional Classification		
class I		5/32 (16%)
class II		17/32 (53%)
class III		10/32 (31%)
class IV		0/32 (0%)
Ischaemic aetiology		22/32 (69%)
LVEF (%) with echo	31.5 ± 10.6	31/32 (97%)
Syncope/presyncope		5/32 (16%)
Acute myocardial infarction		7/32 (22%)
Chronic myocardial infarction		17/32 (53%)

ICD — implantable cardioverter-defibrillator; SD — standard deviation; LVEF — left ventricular efection fraction; NYHA — New York Heart Association

In order to take into account the above-mentioned exceptions, a separate analysis of conservative DFTs was performed. A conservative DFT was defined as:

— 30 J for the two DFTs with the non-6996S lead configuration where the necessary backup shocks were obtained with 34 and 35 J;
— the lowest possible DFT in the four non-6996S configurations that deviated from the Binary Search Protocol;
— raw DFT in all other cases.

Note that this definition of conservative DFT assumes that all shocks at non-tested energy levels were successful in the non-SQ lead configurations, and unsuccessful in the configurations with SQ lead.

To evaluate the difference between DFT with and without SQ leads, a single-sided paired t-test was performed. The assumptions of the t-test were met, as the sample size was large enough (n = 31) and the differences were statistically significant. The $DFT_{Can \rightarrow RV}$ and $DFT_{Can + 6996S \rightarrow RV}$ were 14.3 ± 9.9 J and 10.5 ± 6.2 J respectively (p = 0.007, α = 0.025) (Fig. 4).

The results were similar with conservative DFT values: $DFT_{Can \rightarrow RV}$ and $DFT_{Can + 6996S \rightarrow RV}$ were 13.1 ± 8.3 J and 10.5 ± 6.2 J respectively (p = 0.01, α = 0.025).

The correlation coefficient between the initial and second DFT values in the same patient was assumed to be equal to 0.53 using the protocol for equal configurations — a value derived from the evaluation studies of the 6996 lead (ACAT II study). Figure 5 presents the DFT results for each patient, obtained for the two configurations with alternative testing patterns. The actual coefficient of correlation between both DFT values was 0.57.

Figure 6 shows the cumulative DFT distributions of Can → RV and Can + 6996S → RV configurations, that indicate the fraction meeting the implant criterion of 18 J ICD as defined in the clinical protocol of 74.2% and 93.5% respectively. A Fisher test for proportions resulted in a two-sided p-value of 0.08 for the raw DFTs, and in a two-sided p-value of 0.15 for the conservative DFTs.

With the normality assumption for t-test not met, for testing whether using amiodarone leads to a higher DFT (Tab. 2),

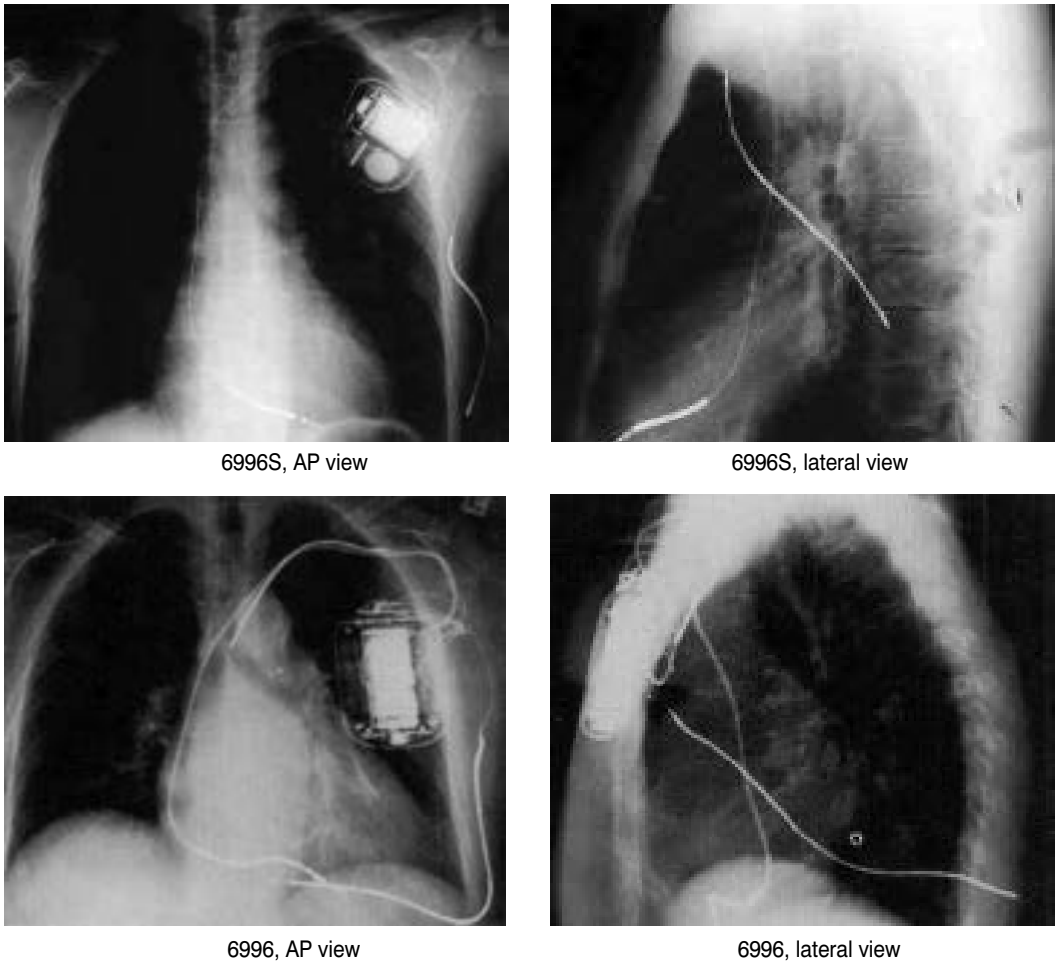

Figure 3. Typical examples of anterior-posterior and lateral X-ray images of the intended 6996S and 6996 implant positions taken from one of the patients in the 6996S study and from a 6996 patient as a reference

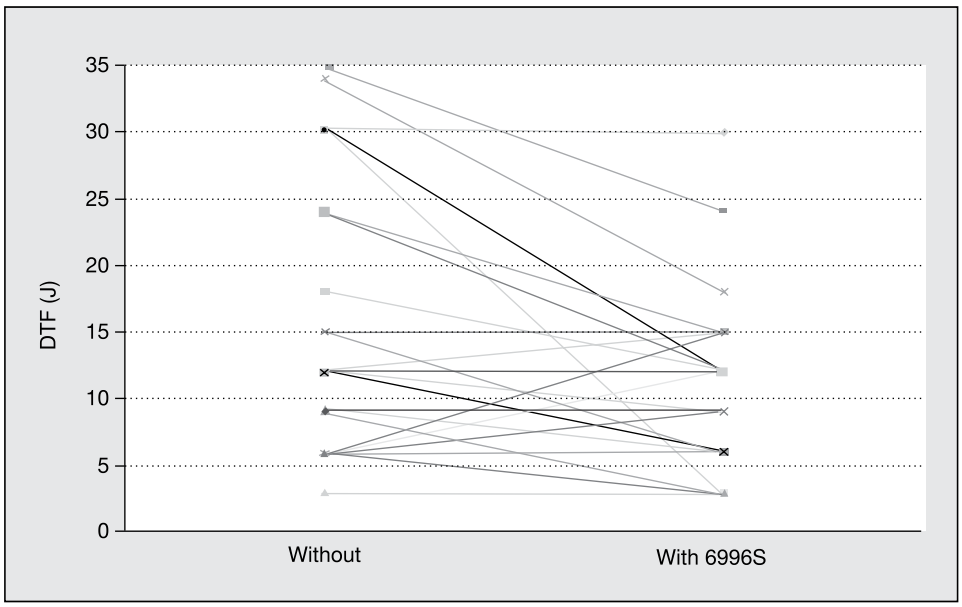

Figure 4. DFT obtained from raw DFT data of ICD configurations without and with one lead model 6996S (n = 31)

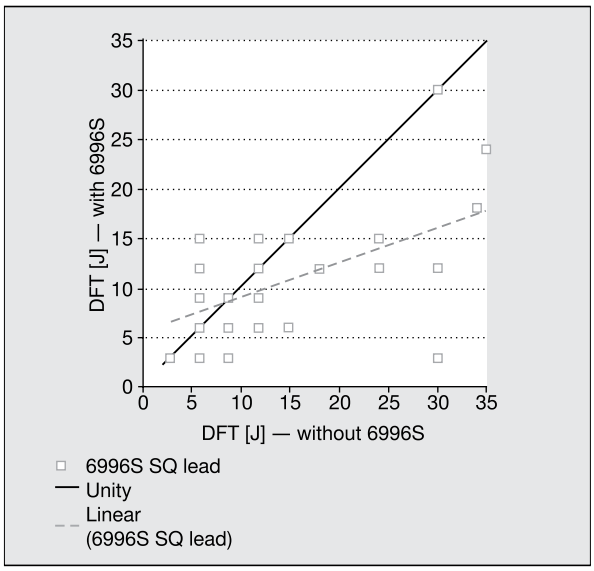

Figure 5. DFT for configuration with 6996S plotted against DFT for configuration without 6996S

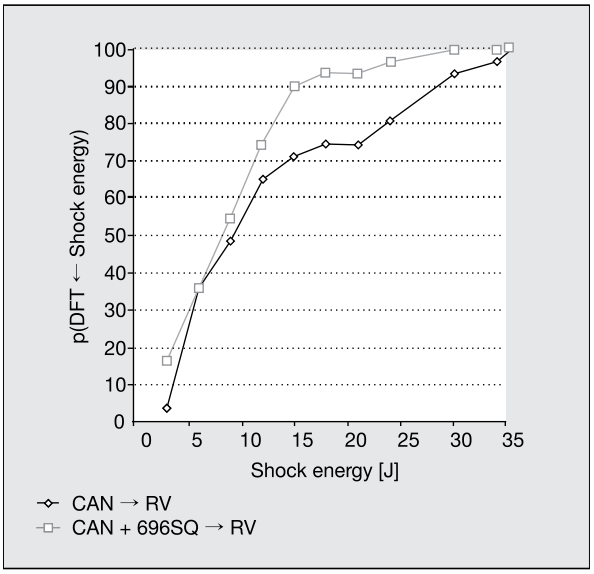

Figure 6. Cumulative DFT distribution of Can → RV and Can + 6996S → RV configurations

the non-parametric Wilcoxon two sample test was used. The DFT values obtained without SQ were not significantly different in patients with versus without amiodarone ($p = 0.45$), also for the conservative DFT values ($p = 0.33$). Also, no significant differences in DFT with SQ were seen in patients with versus without amiodarone ($p = 0.08$), even though the p value approximated to the level of significance. The conservative DFTs with SQ were equal to the raw DFT values.

During the study, adverse events were observed in eight (26%) patients. All adverse events and their outcomes are summarised in Table 3. The most frequent complication during the entire follow-up period was progression of heart failure, but only in one case did it occur on the day of ICD implantation, and this was not related to the procedure. None of the adverse events were related to the implant procedure or the chronic performance of the investigated lead model.

Mean DFT impedance at DFT shock energy for the Active Can → RV test configuration ($n = 30$) was significantly higher than for the Active Can + 6996S → RV test configuration ($n = 30$) — respectively $63.4 \pm 8.9\ \Omega$ and $50.3 \pm 7.4\ \Omega$ ($p < 0.0001$).

Similarly, a significantly higher value of mean DFT impedance at 30J shock energy was observed for the Active Can → RV test configuration ($n = 26$) compared to the Active Can + 6996S → RV test configuration ($n = 30$) — respectively $65.0 \pm 8.4\ \Omega$ and $50.0 \pm 6.3\ \Omega$ ($p < 0.0001$).

X-ray images of patients with chronically implanted 6996S leads were visually examined. Coil retraction was estimated according to lateral and A-P views at the beginning and at the end of the follow-up period. Radiological reference points were vertebrae, tissue structures, metal sutures, and eventually the electrodes of other leads. Given small angular inter-patient differences in X-ray images, resulting from the small alterations in the position and orientation of the X-ray source relative to the patient's thorax, the accuracy of coil retraction estimation is limited to approximately 1–2 cm. X-rays from at least two follow-up episodes were available from 14 patients who received a chronic 6996S implant. The episodes and retraction results are shown in Table 4. The estimated tip retraction was zero ($n = 6$), 1 cm ($n = 2$), 3 cm ($n = 1$) and 4 cm ($n = 1$), with a mean value of 1.2 ± 1.3 cm. Two patients had both one- and three-month follow-ups, showing no additional displacement.

Discussion

Implantation of ICD is nowadays the main therapeutic approach in patients with life-threatening arrhythmias as well as in those with no arrhythmic events but with markedly impaired left ventricular function [4–9]. Efficient and safe treatment of patients with ICD depends on proper settings of the device, including a sufficient safety margin of energy delivered during defibrillation. Therefore defibrillation threshold testing is a pivotal element of the implantation procedure in many clinical centres. There are various possible approaches to defibrillation threshold testing, primarily regarding its specific dimensions such as timing and method [10]. Moreover, taking into account the presumed perils of cardiac arrest, many centres do not include this

Table 2. DFT distributions categorised for 6996S — no 6996S, and amiodarone — no amiodarone

DFT	All	Amiodarone	No amiodarone
All		14.1 ± 8.8 J (n = 15)	10.7 ± 7.9 J (n = 16)
6996S	10.5 ± 6.2 J (n = 31)	12.2 ±6.2 J (n = 15)	8.8 ± 5.9 J (n = 16)
No 6996S	14.3 ± 9.9 J (n = 31)	16.1 ± 10.7 J (n = 15)	12.7 ± 9.2 J (n = 16)

Table 3. Summary of all observed adverse events

Patient	Description	Nr days post-implant	System related	6996S related	Procedure related	Action	Adverse event resolved
001	Patient died due to heart failure	49	No	No	No		–
003	Colitis induced by antibiotics	–7	No	No	No	Cefnoxin therapy	Yes
004	Significant increase in IEGM	1	Yes	No		Reposition RV lead; 15 J test shock successful	Yes
005	Shocks in sinus tachycardia	67	No	No	No	Modify therapy and reprogramme ICD	Yes
011	Ischaemic stroke	88	No	No	No		Yes
013	Ventricular tachycardia and ICD therapies	41	No	No	No	Increase dose of beta--blocker; reprogramme ICD	Yes
015	Pulmonary oedema	90	No	No	No	Diuretic pharmacotherapy	Yes
024	Progression of heart failure symptoms	0	No	No	No		Yes

Table 4. 6996S tip displacement

Patient	Initial X-ray	Second X-ray	Estimated tip retraction [cm]
6996002	PHD	3 M	2
6996003	PHD	3 M	2
6996005	PHD	1 M	3
6996013	PHD	1 M	1
6996014	PHD	1 M	2
6996015	PHD	1 M	0
6996018	1 M	3 M	0
6996020	PHD	1 M	0
6996021	PHD	1 M	1
6996023	PHD	1 M	2
6996026	PHD	1 M	0
6996029	PHD	1 M	4
6996031	PHD	1 M	0
6996032	PHD	1 M	0

PHD — follow up at hospital discharge; 1M — one month follow-up; 3M — three month follow-up

procedure at all in their standard approach [11]. The complication rate of routine DFT testing however is very low (less than 0.2%) [12]. One of the important advantages of DFT testing is the assessment of successful conversion of ventricular fibrillation to sinus rhythm with a safety margin of maximal output of the ICD (usually ≥ 10 J). In the literature there is plentiful data regarding this problem and showing a large dispersion of incidence of high DFT among ICD patients, ranging from 3 to 12% [13–16].

The presence of a high defibrillation threshold and its probabilistic character warrant taking adequate action in order to lower the threshold. In modern devices there are some software-based solutions to this problem. The most important one is the possibility of changing shock polarity or defibrillation impulse waveform [17]. Another way to resolve the problem of a high defibrillation threshold is the implantation of a subcutaneous array or patch.

Subcutaneous leads were introduced into the trouble-shooting armentarium for high defibrillation threshold in ICD devices in the 1990s. Due to the technical development, it was possible to replace patches with arrays, with the latter ones initially constructed as three-finger designs, subsequently evolving into single-body subcutaneous leads [18].

There are convincing published findings confirming that the application of SQ leads is a very effective way of reducing the defibrillation threshold both in short and long-term observations [19–22]. However, as with every invasive procedure, implantation of SQ lead may lead to difficulties or complications. Periprocedural complications are very rare (e.g. pneumothorax) but long-term lead-related complications occur in 7–9% of cases (infections, dislocations) [18]. They are independent of the type of SQ lead and are discovered by detailed follow-up consisting of serial chest radiographs and repeated DFT testing. Some authors claim the single-element leads to be superior due to their higher feasibility of implantation [18, 20].

In the present study, we investigated a new model of single-element subcutaneous defibrillation leads. The lead was designed to improve the ease of use compared to a previously market-released model 6996. The main difference between these two types is the coil length (25 cm vs 15 cm). The length of the coil in the 6996S lead was chosen based on computer modelling showing that a SQ lead with 12 cm coil length was able to further reduce DFT by roughly 70% of the reduction calculated for the 25 cm coil model 6996 [23]. The tip of the 6996 lead is placed on a patient's back, and is wrapped around the lateral wall of the thorax. The shorter 6996S lead ends at the lateral wall of the thorax in the medial axillary line.

The main finding of our study is a significant reduction of defibrillation threshold achieved by adding the studied lead to a conservative ICD system configuration, although problems with enrollment of a sufficient number of patients existed.

The binary search protocol was deviated from for the CAN → RV configurations in five patients because of unsuccessful defibrillation attempts at lower test energies and the necessity of using back-up ICD shocks. In these patients, successful defibrillation energy of a test shock or backup shock were considered the DFT values. The data from these patients was not excluded from the study. The lowest successful back-up shock energy was regarded as the DFT. Such an approach concerning the back-up shocks as surrogates for DFT was used only in patients without the 6996S lead. Thus, these higher DFTs (resulting from deviations of the binary search protocol) increased the DFT difference between the group without and the group with the 6996S lead, and reduced the p-value in the statistical comparison. In order to ensure that the statistical significance of the DFT difference was not due to the inclusion of these DFTs, a conservative DFT was defined as one energy level above the highest failed test energy level, which in turn is the lowest possible DFT that could have been obtained, with a compliant protocol execution. This definition of a conservative DFT assumes that all test shocks missing in the protocol would have been successful. According to the above-mentioned problems, we also searched for statistical significance of the conservative DFT reduction. Both types of data used revealed a significant reduction in DFT with the addition of the 6996S lead.

To the best of our knowledge, in unselected populations of patients from different centres, the mean DFT is approximately ≤ 10 J [24, 25]. According to the results of our study, we stated that the mean defibrillation threshold was higher than expected, based on the above-mentioned literature data. The higher DFT values seen in our study made it possible to demonstrate the ability of the 6996S lead to significantly reduce DFT in high-DFT patients, normally only sparsely represented in other study populations.

One of the strongest predictors of a higher defibrillation threshold is chronic administration of amiodarone [17] but data regarding this problem is conflicting [26]. In our study, we did not observe differences in values of DFT according to the chronic treatment of amiodarone.

An important finding of our study is the demonstration of significant defibrillation impedance reduction with the 15 cm coil lead. This observation is of practical relevance since the application of single coil leads and active can systems produces higher defibrillation impedance compared to dual coil leads (RV + SVC system),

while decreasing DFT by subcutaneous leads is associated with the reduction of DF impedance.

Model 6996S was relatively stable, although in a considerable minority withdrawal of the coil was observed up to 4 cm, potentially resulting in a DFT increase higher than the 1.2 J (based on the regression analysis). This increase, although acceptable in the study, may be unacceptable in future clinical practice when the 6996S lead is implanted in high DFT patients.

Therefore, provisions in the lead design that would enhance lead stability, such as distal and proximal fixation, are expected to improve the stability of DFT and lead position.

Acknowledgement

We thank Mr Karel Smits MSc and Mark Lazerroms PhD MSc, Medtronic Bakken Research Center, Mastricht, The Netherlands for their help to conducting the study and edition this publication.

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