Causes of redo procedures in patients with an implantable cardioverter-defibrillator – long-term follow-up results

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Abstract

Background: Implantation of a cardioverter-defibrillator (ICD) is a well-established method to prevent sudden cardiac death (SCD). Due to the expanding indications for this type of treatment and increasing survival of these patients, the ICD population is growing rapidly.

Aim: To assess the rate and causes of reoperations in patients with ICD over a long-term (at least 4 years) follow-up period.

Methods: Between 1995 and 2006, an ICD was implanted in 598 patients. This study included all patients with a follow-up duration of at least 4 years and only those who underwent a repeat procedure later than 6 weeks after the index ICD implantation.

Results: The study group consisted of 174 patients with a mean age of 51±18 years who were followed for a mean of 6±1.7 years. Coronary artery disease (CAD) was diagnosed in 92 (53%) patients, and non-ischaemic cardiomyopathy in 82 (47%) patients. Prophylactic ICD therapy was instituted in 11 (6%) patients, whereas 163 (94%) patients received ICD for secondary prophylactics. During the follow-up period, 10 deaths occurred: 6 of all deaths (60%) in patients with CAD and 4 of all deaths (40%) in the non-ischaemic group. A total of 211 redo procedures in 139 patients were performed. Indications for repeat procedures included battery depletion in 136 patients, ICD malfunction in 37 cases, infection related to the implanted system in 5 patients, problems with leads in 19 cases, an upgrade to the dual-chamber system in 5 or to the biventricular system in 3 patients, and the revision of an ICD pocket in 6 patients.

Conclusions: Repeat procedures in ICD recipients are frequent. The most common cause is battery depletion and ICD replacement indicated by a manufacturer. Improvement in ICD technology is essential to increase ICD longevity and decrease the redo-procedure rates. Patients with ICD should be regularly followed in experienced centres in order to detect ICD system failure early.

Key words: implantable cardioverter-defibrillator (ICD), complications, repeat procedures

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Introduction

Implantable cardioverter-defibrillators (ICD) have been used in clinical practice for more than 25 years. The first ICD implantation took place in 1980 and was performed by Dr Michael Mirowski and his team. Initially, the devices had only defibrillating capabilities. Because of their large size, they were implanted in the abdominal area and electrodes were placed epicardially using thoracotomy. During the last 20 years dynamic progress in this field has been made. Current devices are smaller, electrodes are inserted endocardially using venous access and diagnostic as well as therapeutic options have been expanded.

Nowadays, ICD implantation is the method of choice for the treatment of survivors of sudden cardiac death (SCD) due to ventricular fibrillation (VF) or sustained ventricular tachycardia (sVT) [1]. It is also used for primary prevention in those who are at increased risk of SCD [2-4].

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Table I. Causes of redo procedures in studied patients

Indication	Number of procedures (number of patients)	% of all redo procedures
Battery depletion (elective replacement)	136 (90)	64.5
ICD failure	37 (34)	17.5
Lead problems	19 (19)	9.0
Pocket infection	5 (5)	2.4
Pocket revision	6 (5)	2.8
Upgrade to biventricular system	3 (3)	1.4
Upgrade to dual-chamber ICD (DDD)	5 (5)	2.4

The widening indications for ICD therapy has resulted in an increased number of device implantations, which is associated with an enhanced risk of both early and late complications. The ICD implantation procedure itself is similar to a typical pacemaker insertion. However, induction of VF and defibrillation threshold testing are additional important elements of the implantation procedure. The follow-up in ICD patients is much more difficult than in pacemaker patients. Problems with device functioning or lead failure may result both in inadequate therapies as well as in a failure to terminate VF or sVT, which may be lethal. Another significant complication are psychological problems, including depression, which are closely associated with ICD discharges and are due to the fear of possible incoming ICD shock [5].

The aim of this study was to assess the rate and causes of repeat procedures in patients with ICD during a long-term (at least 4 years) follow-up.

Methods

Between July 1995 and August 2006, ICD implantation was performed in our institution in 598 patients. Of those, the follow-up duration was longer than 4 years in 174 patients (126 males, mean age 51±18 years), who formed the analysed group. Only redo procedures performed later than 6 weeks after the initial implantation were taken into account. The underlying disease was coronary artery disease (CAD) in 92 (53%) patients, whereas 82 (47%) patients had non-ischaemic cardiac pathology (non-CAD group). In the vast majority of patients (163 – 94%) the ICD was implanted for the secondary prevention of SCD, and in the remaining 11 (6%) – for primary prevention.

In the first four patients transvenous leads were implanted using tunnelling to the device pocket, located in the abdomen. In all the remaining patients devices were implanted in the subclavicular area, subcutaneously or under the pectoral muscle. Antibiotics (intravenous cephalosporines) were routinely given, initially for five days, and later for three days. In patients treated with prolonged oral anticoagulation these agents were stopped three days before the procedures and the patients received unfractionated heparin.

Statistical analysis

Results are presented as mean ± standard deviation or numbers and percentages. Continuous variables which were normally distributed were compared using the Student t-test, whereas data not normally distributed were compared using the Wilcoxon test. A p value <0.05 was considered statistically significant. The SAS 8.0e statistical package was used.

Results

During a mean follow-up of 6±1.7 years (median 5.5, range 4-10 years) a total of 211 redo procedures were performed in 139 patients (Table I). The most frequent indication was elective replacement due to battery depletion, followed by device malfunction, lead problems, upgrading to DDD or biventricular pacing mode, infection and ICD pocket revision.

Lead problems were an indication for redo procedures in 19 patients and were detected during the routine follow-up visits. The most frequent consequences of lead failure were inadequate ICD discharges (11 patients), followed by an increase in the pacing threshold (3 patients), too low amplitude of intracardiac signals (3 patients), pectoral muscle stimulation (1 patient) and inadequate ICD discharges due to T wave oversensing, requiring lead reposition (1 patient). Concomitant ICD generator replacement was necessary in one patient due to the capacitor failure (manufacturer notice) and in another nine due to the battery depletion resulting in inadequate ICD shocks. In addition, in four patients undergoing elective device replacement, insulation failure of a pacing (2 patients) or defibrillating lead (2 patients) was found which required new lead implantation (in Table I these indications are reported as ICD replacement).

Infection of an ICD pocket occurred in four patients, whereas one patient developed infective endocarditis (IE). Three of them had previously undergone ICD replacement, including one revision due to inadequate therapy because of T wave oversensing. In the remaining two patients this was the first implanted device. In four patients the whole system (device and leads) was removed in the cardiosurgical operating room. Following a three-week antibiotic therapy, a new system was implanted in the left subclavicular region (three patients with abdominal ICD location) or right subclavicular area

(one patient with an ICD implanted initially in the left subclavicular region). In one female patient who had no fever, no leucytosis, negative blood cultures and no echocardiographic signs suggesting IE, only an ICD box was removed. A new system was implanted in the same place following a three-week antibiotic therapy. A further follow-up of these patients was uneventful.

The ICD pocket revision was performed in six patients and was due to imminent decubitus ulcer (two patients), device dislocation (one patient) and fistula (three patients). In the first three patients a new ICD pocket was created. In patients with skin fistula (one of them had previously pocket revision due to imminent decubitus ulcer) the whole system was removed, and a new system was implanted at the opposite side. In all patients with fistula blood cultures were negative.

An ICD malfunction occurred in 34 patients, including three patients who had this complication twice, which resulted in a total of 37 redo procedures. Almost all device failures (36 procedures) occurred in an ICD produced by a single manufacturer and only one in a device of another manufacturer. In the first case, the manufacturer announced the failure (prolonged time of capacitor charging) and all patients with malfunctioning devices underwent ICD replacement. In a patient with an ICD from a different company, a lack of communication between device and programmer was a reason for replacement. Both companies provided new devices for free.

Ten patients died during follow-up – 6 (60%) from the CAD group and 4 (40%) from the non-CAD group. None of deaths could have been attributed to the redo procedure or complications which prompted repeat procedure.

Discussion

The results of the present analysis indicate that redo procedures in patients with ICD are relatively frequent. The most common indication is elective device replacement due to a battery depletion, which accounted for 65% of procedures in our patients. These are routine procedures and usually do not expose a patient to a significant risk. However, it is worth remembering that each replacement increases the risk of infection, decreases patient's quality of life and raises costs [6].

Whereas pacemaker failure usually is not life-threatening (except for pacemaker-dependent patients), ICD failure in patients with a history of aborted SCD or who are at high risk of SCD may be fatal. In addition, contrary to pacemaker failure, there is no way of detecting ICD malfunctioning other than during a control visit in a specialised centre. The majority of patients with ICD are not paced and have their own, intrinsic heart rhythm when the ECG is recorded. This is because the ICD is usually programmed to a low pacing rate with the exception of patients with complete atrioventricular block, biventricular system, long QT syndrome or bradycardia. Moreover, proper pacing parameters do not exclude failure of a defibrillating electrode.

An ICD failure was found in 24% of our patients and in the majority of cases was announced by the manufacturer. According to the FDA report, the rate of ICD malfunctioning has been increasing in recent years and is far more frequent than pacemaker failure [7]. It is worth noting that all companies selling ICDs in Poland provide detailed information on all abnormalities found in their devices [8].

Lead problems occur in 1-14% of ICD patients and usually are detected during a routine follow-up visit. These problems include low amplitude of intracardiac ECG, increased pacing threshold, abnormalities of the high-voltage or low-voltage electrode systems or inadequate ICD discharges, which lead to complete battery depletion. More dangerous are 'asymptomatic' abnormalities, which are usually detected during ICD replacement and consist of a high defibrillation threshold, especially in older devices where the impedance of a defibrillating electrode cannot be measured without shock induction.

In 440 consecutive patients with ICD followed by Alter et al. [9] for a mean of 46±37 months, the rate of redo procedures performed due to lead problems was 12%, which is similar to our findings. However, these authors also included an early post-operative period in the analysis which might increase the number of redo procedures. The follow-up duration was almost two times longer in our study than in that of Alter et al., which is an important difference because complication rate associated with lead problems increases with time. Luria et al. [10] found that the only independent predictor of lead failure was abdominal implantation of ICD (20 vs. 4% for an ICD implanted in the subclavicular area). In our study only four patients had such a system implanted and one had lead repositioning due to T wave oversensing. However, the number of our patients with this complication is too small to draw any conclusions.

It has been reported that the rate of redo procedures due to lead malfunctioning was higher in patients with dual-chamber systems than in those with VVI-ICD (18 vs. 10%) [9]. However, this was exclusively due to electrode dislocation (12% DDD vs. 3% VVI), whereas the rate of complications associated with electrode or insulation failure was two times higher in the VVI-ICD recipients. In our cohort, the number of repeat procedures due to lead problems was similar in both groups (13% DDD vs. 11.7% VVI); however, others reported a higher complication rate in DDD-ICD

systems [9, 11]. Similarly to Alter et al. [9] data, lead failure was more frequent in VVI-ICD than in DDD-ICD systems (11 vs. 4.3%), whereas electrode dislocation was more common in DDD-ICD systems (8.6 vs. 1.5%).

Infection is a very serious complication which may lead to severe symptoms, sepsis and even death. Predisposing factors include diabetes, altered immunological reaction and a history of ICD replacement or revision. This is why antibiotics should be administered in patients undergoing ICD replacement [12]. The proportion of patients with a pocket infection varies from 0 to 6.7% [13]. Such a wide range of reported infection rates is due to the differences in the period when ICD was implanted (early studies reported infection rate up to 27%), variable duration of follow-up (the shorter the follow-up period, the lower the complication rate), different locations of ICD pocket (abdominal site was associated with increased risk of infection) [13], and also differences in the clinical characteristics of the studied patients.

Some authors suggest that an infected ICD pocket may be treated locally. Others, including us, believe that the whole system should be explanted due to the risk of IE and a new system should be implanted at the opposite side [14, 15]. In our study the infection rate was 2.4%, which is similar to that reported by others. Of note, the follow-up duration in our study was very long (72±18 months), whereas in other reports it ranged from 10 to 30 months. In our group of patients, infection occurred at a mean of 3.7±1.8 years after the first ICD implantation. Two of our five patients with this complication had already undergone ICD replacement and one patient had previous lead reposition due to inadequate ICD therapy as well as a device replacement. All these three patients had abdominal location of ICD. It has been well documented that both repeat procedures and abdominal location of ICD are risk factors of infection [13, 16]. It is also noticeable that in our study the infection rate decreased over time, which can be attributed to the learning curve [17]. The ongoing progress in ICD and lead technology enabled construction of more reliable equipment and made the implantation procedure easier, which resulted in shortening of the procedural time and a decrease in the complication rate.

Currently, there are no uniform recommendations as to how often follow-up visits should be performed. The majority of authors advocate reviewing patients with ICD at three-month intervals, which may help in early detection of possible ICD malfunction. However, due to the growing number of patients receiving ICD (longer survival and wider indications for implantation) this task is more and more difficult to fulfil. The solution would be widespread use of telemetric follow-up and constant training of increased numbers of medical personnel in specialised implantation centres.

In conclusion, redo procedures in patients with ICD are frequent. More than one third of repeat procedures are due to ICD malfunctioning, lead failure or infection. Detailed and systematic follow-up in experienced centres is essential for the patient's safety and early detection of ICD abnormalities. Constant training of medical personnel and increase in their number are also very important.

References

1. A comparison of antiarrhythmic-drug therapy with implantable defibrillators in patients resuscitated from near-fatal ventricular arrhythmias. The Antiarrhythmics versus Implantable Defibrillators (AVID) Investigators. *N Engl J Med* 1997; 337: 1576-84.
2. Moss AJ, Zareba W, Hall WJ, et al. Prophylactic implantation of a defibrillator in patients with myocardial infarction and reduced ejection fraction. *N Engl J Med* 2002; 346: 877-83.
3. Bardy GH, Lee K, Mark DB, et al. Amiodarone or an implantable cardioverter-defibrillator for congestive heart failure. *N Engl J Med* 2005; 352: 225-37.
4. Zipes DP, Camm AJ, Borggrefe M, et al. ACC/AHA/ESC 2006 guidelines for management of patients with ventricular arrhythmias and the prevention of sudden cardiac death – executive summary: A report of the American College of Cardiology/American Heart Association Task Force and the European Society of Cardiology Committee for Practice Guidelines (Writing Committee to Develop Guidelines for Management of Patients with Ventricular Arrhythmias and the Prevention of Sudden Cardiac Death) Developed in collaboration with the European Heart Rhythm Association and the Heart Rhythm Society. *Eur Heart J* 2006; 27: 2099-140.
5. Bilge A, Ozben B, Demircan S, et al. Depression and anxiety status of patients with implantable cardioverter defibrillator and precipitating factors. *Pacing Clin Electrophysiol* 2006; 29: 619-26.
6. Hauser RG. The growing mismatch between patient longevity and the service life of implantable cardioverter-defibrillators. *J Am Coll Cardiol* 2005; 45: 2022-5.
7. Maisel WH, Moynahan M, Zuckerman BD, et al. Pacemaker and ICD generator malfunctions: (www.fda.gov/cdrh/ocd/icd/abstract.html)
8. Przybylski A, Sterliński M. Implantowane kardiowertery-defibrylatory. *AiM*, Warszawa 2005.
9. Alter P, Waldhans S, Plachta E, et al. Complications of implantable cardioverter defibrillator therapy in 440 consecutive patients. *Pacing Clin Electrophysiol* 2005; 28: 926-32.
10. Luria D, Glikson M, Brady P, et al. Predictors and mode of detection of transvenous lead malfunction in implantable defibrillators. *Am J Cardiol* 2001; 87: 901-4.
11. Takahashi T, Bhandari AK, Watanuki M, et al. High incidence of device-related and lead-related complications in the dual-chamber implantable cardioverter defibrillator compared with the single-chamber version. *Circ J* 2002; 66: 746-50.
12. Ellenbogen K, Wood M (eds.). Cardiac pacing and ICDs. 4th ed. *Blackwell Publishing* 2005.

13. Mela T, McGovern BA, Garan H, et al. Long-term infection rates associated with the pectoral versus abdominal approach to cardioverter- defibrillator implants. *Am J Cardiol* 2001; 88: 750-3.
14. O'Nunain S, Perez I, Roelke M, et al. The treatment of patients with infected implantable cardioverter-defibrillator systems. *J Thorac Cardiovasc Surg* 1997; 113: 121-9.
15. Bracke FA, Meijer A, van Gelder LM. Lead extraction for device related infections: a single-centre experience. *Europace* 2004; 6: 243-7.
16. Harcombe A, Newell S, Ludman P, et al. Late complications following permanent pacemaker implantation or elective unit replacement. *Heart* 1998; 80: 240-4.
17. Al-Khatib SM, Lucas FL, Jollis JG, et al. The relation between patients' outcomes and the volume of cardioverter-defibrillator implantation procedures performed by physicians treating Medicare beneficiaries. *J Am Coll Cardiol* 2005; 46: 1536-40.

Przyczyny reoperacji u chorych z wszczepionym automatycznym kardiowerterem-defibrylatorem – obserwacja odległa

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Streszczenie

Wstęp: Automatyczne kardiowertery-defibrylatory (ICD) są uznaną metodą leczenia chorych z wysokim ryzykiem nagłego zgonu sercowego. Coraz szersze wskazania do wszczepienia ICD wiążą się z rosnącą liczbą implantacji, a tym samym większym ryzykiem powikłań.

Cel: Ocena częstości i przyczyn reoperacji u chorych z wszczepionym ICD obserwowanych przez co najmniej 4 lata.

Metodyka: W latach 1995–2006 wszczepiono ICD u 598 chorych. Do badania włączono pacjentów obserwowanych minimum 4 lata. Analizowano wyłącznie zabiegi, które odbyły się później niż 6 tygodni po zabiegu wszczepienia ICD.

Wyniki: Oceniono 174 chorych w średnim wieku 51,0±17,5 roku. Okres obserwacji wyniósł średnio 6±1,7 roku. Chorobę wieńcową (CAD) rozpoznano u 92 (52,8%) chorych, a u 82 (47,2%) niewieńcową kardiomiopatię (non-CAD). Kardiowertery-defibrylatory wszczepiono w ramach profilaktyki pierwotnej u 11 (6,2%) chorych i u 163 (93,8%) chorych w ramach profilaktyki wtórnej. Zanotowano 10 zgonów: 6 (60%) w grupie CAD i 4 (40%) w non-CAD. Nie stwierdzono żadnego zgonu mogącego być wynikiem reoperacji lub też powikłań będących wskazaniem do zabiegu. Podczas obserwacji wykonano 211 reoperacji u 139 chorych. Przyczyną zabiegów były: wyczerpanie baterii urządzenia (136 zabiegów), uszkodzenie ICD (37), zakażenie układu (5), komplikacje związane z elektrodą (19), *upgrade* systemu do układu dwujamowego (5) lub resynchronizującego (3), rewizja loży (6). Problemy związane z elektrodą były przyczyną 19 reoperacji i zostały wykryte podczas rutynowej kontroli ICD. Uszkodzenie elektrody najczęściej objawiało się nieadekwatnymi wyładowaniami ICD (11 chorych). W pozostałych przypadkach przyczyną reoperacji był wzrost progu stymulacji (3 chorych), niezadowalające wartości impulsu własnego (3 chorych), stymulacja mięśnia piersiowego (1 chory), nieadekwatne wyładowania związane z nadczułością załamka T (1 chory). W jednym przypadku z powodu fabrycznego uszkodzenia kondensatorów, a w 9 ze względu na wyczerpanie baterii spowodowane nieadekwatnymi wyładowaniami, konieczna była – obok implantacji nowej elektrody – wymiana generatora ICD. Ponadto u 4 chorych w trakcie planowej wymiany ICD stwierdzono uszkodzenie osłonki elektrody (2 chorych) lub elektrody defibrylującej (2 chorych). Uszkodzenie elektrody częściej zdarzało się w układach jednojamowych 11 *vs* 4,3%, a dyslokacja w dwujamowych 8,6 *vs* 1,5%. U 4 chorych wystąpiły cechy infekcji loży ICD, a u jednego infekcyjne zapalenie wsierdzia; średnio po 3,7±1,8 roku. U 4 chorych usunięto układ łącznie z elektrodami, a następnie po 3-tygodniowej antybiotykoterapii implantowano nowy układ. U jednej pacjentki usunięto jedynie korpus urządzenia. Nowy układ wszczepiono po przeciwnej stronie. Przyczyną 6 rewizji loży po wszczepieniu ICD były: zagrażająca odleżyna (2 zabiegi), dyslokacja ICD (1) i przetoka (3). W pierwszych 3 przypadkach zmieniono lożę ICD. U pacjentów z przetoką skórną usunięto dotychczasowy układ, łącznie z elektrodami, a następnie implantowano ICD z nowymi elektrodami po stronie przeciwnej. U wszystkich chorych z przetoką uzyskane posiewy były jałowe. Uszkodzenie ICD było przyczyną 37 zabiegów i w większości przypadków było zgłaszane przez firmy produkujące te urządzenia.

Wnioski: Reoperacje u chorych z ICD są częste. Najczęstszą przyczyną są niedoskonałości techniczne urządzeń. Poprawa technologii aparatów jest niezbędna, aby wydłużyć czas pracy ICD i zmniejszyć częstość zabiegów. Dokładna i systematyczna kontrola ICD w doświadczonych ośrodkach jest bardzo ważna dla bezpieczeństwa chorych i pozwala wcześnie wykryć nieprawidłowości funkcjonowania tych urządzeń.

Słowa kluczowe: automatyczny kardiowerter-defibrylator (ICD), powikłania, reoperacje, elektroda

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