Hospital readmission in patients with implantable cardioverter-defibrillators

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Abstract

Introduction: Hospital readmissions are one of the important problems of patients with implantable cardioverter-defibrillators (ICD). Detailed analysis of the causes of rehospitalisations may lead to improved management of ICD patients and eventually limit the number of hospital readmissions.

Aim: Prospective analysis of repeat hospitalisations, their causes and time from discharge to first hospital readmission in a group of patients after ICD implantation. A search for predictors of rehospitalisation was also performed.

Methods: Analysis involved 133 consecutive patients who underwent ICD implantation in the Department of Cardiology, PAM. Rehospitalisation causes were split into cardiac and non-cardiac. An index of repeat hospitalisation was calculated and parameters with a direct impact on rehospitalisation necessity were also evaluated.

Results: One hundred and sixty-seven hospital readmissions of 72 (54%) patients were noted at mean 22±15 months after the primary hospitalisation. Rehospitalisation index per patient for the total follow-up period was 1.26, while for the first year of follow-up it was 0.69. In the case of 42 (32%) patients, 91 (54.5%) hospital readmissions were associated with arrhythmia. In 34 (25.6%) patients, 54 (32.3%) rehospitalisations were not related to arrhythmia, while 20 (15%) patients were hospitalised 22 times (13.2%) for non-cardiac reasons. Mean time to the first readmission, regardless of the reason, was 9±9 months. Predominant causes of repeat hospitalisation were ventricular arrhythmias and worsening of heart failure. Patients with left ventricular ejection fraction (LVEF) below 30% and in functional NYHA class III were readmitted to hospital more frequently for reasons not related to arrhythmia.

Conclusions: Hospital rehospitalisations for cardiac causes in patients after ICD implantation are still frequent. Most of them are caused by ventricular arrhythmia and heart failure. Low LVEF (<30%) and NYHA functional class ≥III are risk factors predicting repeat hospitalisations unrelated to arrhythmia.

Key words: cardioverter-defibrillator, rehospitalisations, predicting factors

Introduction

Implantable cardioverter-defibrillator (ICD) implantation is a first line therapy in patients with sustained, life-threatening ventricular arrhythmias [1]. Many clinical trials have documented the effectiveness of this approach in preventing sudden cardiac death and its superiority to antiarrhythmic drug-based regimens in prolonging the life of such patients [1-4]. In addition, there are increasing data confirming the benefits of ICD implantation for primary prevention in patients with ischaemic heart disease (IHD) accompanied by impaired left ventricular (LV) systolic function [5-8].

The most obvious progress made in ICD technology combines reduction of size and prolongation of device longevity, more simplicity during implantation and cost reduction. Technical developments together with the results of the largest trials determine contemporary indications for ICD therapy.
Patients with severe ventricular arrhythmias are often readmitted to hospital. The precise rate of hospital readmissions is not known and necessity of rehospitalisation following ICD implantation has an important impact on quality of life in this group of patients.

The purpose of this study was prospective analysis of the rate of and reasons for hospital readmission as well as time from the first procedure of ICD implantation to rehospitalisation. A search for predictors of rehospitalisation was also performed.

Methods

Studied population and follow-up

The examined population comprised 133 consecutive patients (105 men and 28 women) who underwent the first procedure of third generation ICD implantation between January 1999 and March 2003. All patients were followed in the Department of Cardiology. The following 88 (66.2%) single chamber and 45 (33.8%) dual chamber devices were implanted: PhyIax XM (Biotronik) in 31 patients, μPhylax (Biotronik) in 31, Belos VR (Biotronik) in 13, Tachos DR (Biotronik) in 38, Belos DR (Biotronik) in 4, Gem II VR (Medtronic Inc.) in 3, PCD 7223 (Medtronic Inc.) in 10 patients, PCD 7250 (Medtronic Inc.) in 1, Profile MD (St. Jude Medical) in 1 and Photon μ VR (St. Jude Medical) in 1 patient. Clinical characteristics of the examined group of patients and baseline arrhythmias are presented in Table I and Table II.

Follow-up concerned the period from the day of ICD implantation to the last follow-up examination or patient’s death. Repeat hospitalisation was defined as every hospital readmission lasting longer than 12 hours. Patients were routinely examined at 1 and 3 months after implantation, then every 6 months or more frequently if necessary. Essential information was obtained directly from patients or by telephone either from them or their general practitioners or by the analysis of appropriate medical records.

Classification of rehospitalisation causes

Rehospitalisation causes were divided into two groups: cardiac and non-cardiac. Additionally, cardiac reasons were classified as either related or unrelated to arrhythmia. Among those associated with arrhythmia the following were distinguished: 1. ventricular tachyarrhythmias with or without ICD defibrillation, 2. supraventricular rhythm disturbances, 3. inadequate ICD therapy, 4. control cardioverter test, 5. complications related to device alone, 6. problems with electrodes, and 7. ICD replacement. Reasons not related to arrhythmia comprised: 1. chronic heart failure (CHF), 2. IHD worsening, 3. uncontrolled arterial hypertension, 4. infective endocarditis, 5. dilated cardiomyopathy, 6. pacemaker syndrome. If the patient was admitted for complex reasons, the predominant one was taken into account in the further analysis. Rehospitalisation classification was based on the agreement of two researchers.

Table I. Clinical characteristics of studied population

| Age [years] | 57 (21-79) |
| Men, n [%] | 105 (78.9) |
| NYHA functional classes III-IV, n [%] | 20 (15.0) |
| LVEF [%] | 36±15 (15-65) |
| Dual-chamber ICD, n [%] | 45 (33.8) |
| Predominant rhythm disturbances, n [%] |
| Ventricular fibrillation | 41 (30.8) |
| Sustained ventricular tachycardia | 64 (48.1) |
| Ventricular fibrillation and tachycardia | 27 (20.3) |
| Supraventricular rhythm disturbances | 25 (18.8) |
| AAD at discharge n [%] | 131 (98.5) |
| β-blockers | 88 (66.2) |
| Amiodarone | 72 (54.1) |
| Sotalol | 16 (12.0) |
| Mexiletine | 4 (3.0) |
| Diltiazem | 1 (0.8) |
| Patients without AAD at discharge | 2 (1.5) |

n - number, SD - standard deviation, NYHA - New York Heart Association, LVEF - left ventricular ejection fraction, ICD - implantable cardioverter-defibrillator, AAD - anti-arrhythmic drugs

Table II. Predominant diagnoses in the studied population [n [%]]

| IHD | 99 (74.4) |
| DCM | 12 (9.0) |
| Alcohol cardiomyopathy | 1 (0.8) |
| Postinfectious cardiomyopathy | 3 (2.3) |
| Idiopathic ventricular fibrillation | 5 (3.8) |
| HOCM | 2 (1.5) |
| HCM | 3 (2.3) |
| Long – QT syndrome | 3 (2.3) |
| Brugada’s syndrome | 1 (0.8) |
| ARVD | 1 (0.8) |
| Valvular defect | 1 (0.8) |
| Prophylactic implantation | 2 (1.5) |

n - number, CAD - coronary artery disease, DCM - dilated cardiomyopathy, HOCM - hypertrophic obstructive cardiomyopathy, HCM - hypertrophic cardiomyopathy without left ventricular outflow tract obstruction, ARVD - arrhythmogenic right ventricular dysplasia
The rehospitalisation index of each patient was calculated as the number of hospitalisations divided by the total number of patient-years. Data are presented as mean value, maximum and minimum, and standard deviation. U-Mann-Whitney and Kruskal-Wallis tests were used to compare mean values of continuous variables. Factors including age, gender, NYHA functional class, LV fraction (LVEF) and IHD were analysed as potential predictors of time to the first cardiac-related and arrhythmia-related rehospitalisations. In order to perform this analysis patients were split into subgroups of individuals below and above the age of 60 years as well as with LVEF below and above 30%. Power of statistical correlation between two variables was described by means of the Kendall Tau correlation index. Relationships between categorical variables were assessed by means of dichotomous tables, \( \chi^2 \) or Fisher’s exact tests. Probability of rehospitalisation-free survival was calculated with Kaplan-Meier’s test. Impact of continuous variables on time to the first rehospitalisation was estimated using Cox’s hazard model. Gehan and Cox F-tests were used to compare survival free from any hospital readmissions in the various groups of patients. A value of \( p \) less than 0.05 was considered statistically significant.

**Results**

One hundred and sixty-seven rehospitalisations comprising 72 (54.5%) patients after mean follow-up of 22±15 months (range 2 to 77 months) were noted. Rehospitalisation index per patient during the total follow-up period was 1.26, while during first-year follow-up it was 0.69. Arrhythmia-related rehospitalisation index was 0.37. One hundred and forty-five (86.6%) hospital readmissions for cardiac reasons were recorded in the case of 65 (48.9%) patients, including 91 arrhythmia-related rehospitalisations of 42 (31.6%) patients and 54 (32.3%) readmissions of 34 (25.6%) patients for arrhythmia-unrelated reasons.

Twenty-two (13.2%) hospital readmissions for non-cardiac reasons were found in 20 (15%) patients. Mean time from discharge to first readmission was 9±9 months, irrespectively of the reasons. This period was 10±12 months for arrhythmia-related readmissions, 11±11 months for other cardiac reasons and 11±8 months for non-cardiac readmissions.

During total follow-up, 7 (5.3%) patients died at mean 14±12 months after discharge for the following reasons: 1. CHF - 4 (3%) patients, 2. sudden cardiac death - 1 (0.8%) patient, 3. complications after heart transplantation - 1 (0.8%) patient, 4. complications after ICD implantation (pneumothorax, pulmonary artery embolism) - 1 (0.8%) patient.

Distribution of hospital readmissions due to arrhythmia-related and other cardiac causes are shown in Figures 1 and 2. Probability of survival free from arrhythmia-related (and any other cardiac causes) hospitalisation is presented in Figures 3 and 4.

**Arrhythmia-related rehospitalisations**

*Ventricular arrhythmias* Sustained ventricular tachyarrhythmias with multiple adequate ICD defibrillations were responsible for 50 (30%) hospital
readmissions of 26 (19.5%) patients, and without ICD therapy - for 3 (2%) rehospitalisations of 3 (2.3%) patients. The main cause of one of them was unstable IHD treated with percutaneous coronary intervention. In the other patients initiated treatment comprised a change of ICD set-up, pharmacological therapy modification or adequate electrolyte supplementation if necessary. In the three patients mexiletin was introduced, and in another one therapy with propaenone was started. Four patients were enrolled in a clinical trial with azimilide [9]. In the remainder, amiodarone or sotalol was added to the pharmacotherapy or doses of previously used medications were increased.

One patient was readmitted because of multiple inadequate ICD shocks caused by T wave oversensing. Two (1.5%) patients with high defibrillation threshold during predischarge study were readmitted in order to carry out device control tests with reversed impulse polarisation. One patient after a time-consuming implantation procedure and ventricular electrode reposition 5 days later was rehospitalised after 6 months and two control ICD tests were performed.

**Supraventricular arrhythmias** Supraventricular arrhythmias were noted in 25 (18.8%) patients. In most of them atrial fibrillation (AF) (in 21 patients) or atrial flutter (AFL) (in 2 patients) were diagnosed. Two patients had paroxysmal orthodromic atrio-ventricular tachycardia using accessory pathway. In both cases, successful RF ablation was performed.

Supraventricular rhythm disturbances without ICD therapy were responsible for 9 (5%) rehospitalisations in 7 (5%) cases. In one case successful external electrical cardioversion was carried out because of AF.

Similarly, in one patient with AFL intracardiac electrical cardioversion by means of ICD was performed. In each case, programming arrhythmia detection, rhythm stability criteria or in dual-chamber systems advanced differentiating algorithm were employed. One patient underwent RF ablation because of AFL. In two patients with chronic AF, ablation of the atrio-ventricular junction was carried out.

Inadequate therapy with ICD caused by supraventricular rhythm disturbances was found in 13 (10%) patients who did not require repeated hospital readmission. Some modification of device parameters or pharmacotherapy was all that was needed.

**Figure 3.** Kaplan-Meier curve presenting cumulative proportion of survival free from arrhythmia-related rehospitalisations

**Figure 4.** Kaplan-Meier curve presenting cumulative proportion of survival free from arrhythmia-unrelated rehospitalisations

**Figure 5.** Circular graph showing distribution of non-cardiac hospitalisations with percentage of all hospital readmissions
ICD reimplantation was required in 11 (8%) patients (including 2 patients twice) at mean 24±16 months (4 to 50 months) after first device implantation. One device had to be explanted because of infective endocarditis. In one case, multiple ICD defibrillations and device failure caused premature battery depletion. In the remainder, adequate ICD therapy led to elective replacement indication.

Hospitalisations associated with devices and electrodes Lead-related complications caused 2 (1.2%) hospital readmissions in 2 (1.5%) patients. In both, lead dislocation was diagnosed accidentally during routine check-up examination.

Problems associated with the device itself caused 10 (6%) admissions of 5 patients (3.8%). In two cases, haematoma of the ICD bed was seen. Three further patients required surgical intervention because of pocket ulceration and ICD dislocation. In one patient the whole system was explanted because of local and systemic infection.

Other cardiac-related rehospitalisations Reasons unrelated to arrhythmia caused 54 (32%) rehospitalisations and comprised 34 (25%) patients. It was noted that 35 (21%) readmissions in 23 (17.3%) patients were the result of CHF and 12 (7.2%) hospitalisations of 7 (5.3%) patients of IHD exacerbation. Percutaneous revascularisation procedures were carried out on 2 patients. One (0.8%) patient was readmitted because of uncontrolled hypertension. Another one (0.8%) with hypertrophic obstructive cardiomyopathy was hospitalised twice for routine check-up examination after alcohol ablation of the septal branch. Pacemaker syndrome caused 3 (1.8%) hospitalisations of 1 (0.8%) patient. Another one was treated because of infective endocarditis without ICD revision.

Non-cardiac hospitalisations

Twenty-two (13%) hospital readmissions for other than cardiac reasons were noted in 20 (15%) patients. The distribution of these hospitalisations is shown in Figure 5.

Factor predicting rehospitalisations for cardiac and arrhythmia-related reasons

Mean number of all hospitalisations either unrelated to arrhythmia or for cardiac reasons was higher among men than women (p=0.024, p=0.027; p=0.021, respectively). Age and IHD did not significantly influence the number of hospital readmissions. Patients with IHD were markedly older in comparison with those without such diagnosis (p=0.014). The mean number of non-arrhythmia related hospitalisations was significantly higher in patients with LVEF less than 30% (p=0.019). Patients in NYHA functional class III were admitted to hospital for cardiac reasons more often than those in NYHA classes I or II (p=0.010 and p=0.038, respectively). Patients in class I were markedly younger than patients in NYHA classes II and III (p=0.000007 and p=0.0028, respectively). Patients hospitalised for reasons not related to arrhythmia have lower LVEF than those who were not readmitted for these reasons (28.9% vs 38.5%; p=0.001).

No correlations between the time to the first rehospitalisation and age, LVEF or NYHA functional class were found. Only a weak negative correlation between non-arrhythmia related admission and LVEF was noted (R=−0.22).

Hospital readmissions unrelated to arrhythmia were seen more often in men (p=0.006), in patients with LVEF below 30% (p=0.002) and those in NYHA functional class II (p=0.01). Only LVEF below 30% was an independent risk factor of rehospitalisations unrelated to arrhythmia.

Longer survival free from either non-arrhythmia-related or cardiac-related hospital admissions was observed among women (p=0.01). In patients with LVEF below 30%, shorter survival free from rehospitalisations not related to arrhythmia or for any cardiac reasons was observed (p=0.006). Patients in NYHA functional class I lived longer without arrhythmia-unrelated hospital readmissions in comparison to patients found in NYHA functional classes II or III (p=0.004 and p=0.00005, respectively). No correlation between rehospitalisations and type (single- or dual-chamber) or manufacturer of ICD was found.

Discussion

Since the first ICD implantation in a human in 1980 [10] rapid progress in technology as well as clinical effectiveness of ICD in preventing sudden cardiac death has been observed, although this therapeutic method is still rather expensive. Our prospective clinical trial performed on consecutive patients with implanted third generation ICD showed that the rate of hospital readmissions after this procedure remains significant. We noted that LVEF below 30% was an independent risk factor of cardiac and non-arrhythmia-related hospitalisations.

Previously published studies

In the MADIT trial, rate of hospital readmission per patient-year in patients with ICD was 1.03. Meanwhile, this rate for conventional therapy was 1.12. Mean hospitalisation time was 6.3 and 8.1 days, respectively.
Authors registered 360 hospitalisations of 89 ICD patients during 2577 patient-months and 323 readmissions of 92 non-ICD patients followed by 2254 patient-months [11]. The total number of patients enrolled in the two groups was 95 and 101, respectively.

In the AVID study, 942 rehospitalisations among patients treated medically (antiarrhythmic agents) and 978 patients randomised to ICD implantation were noted. 79% and 74% of those hospital readmissions were short stays, while 21% and 26% were visits to the emergency room. According to modified Kaplan-Meier curve analysis, estimated 3-year hospitalisation number was 1555 for patients treated medically and 1582 for ICD patients [12]. Taking into account the total number of patients in both groups, the patient rehospitalisation index during 3-year follow-up was 1.04 and 1.02, respectively.

In the study by Fahy et al., 65 patients were analysed. After mean follow-up of 19 months, 76 cardiac rehospitalisations of 34 (55%) patients were recorded. The hospital rehospitalisation index per follow-up patient-year was 0.72, while for arrhythmia-related hospitalisations it was 0.4. The probability of freedom from cardiac hospitalisation was 0.57 in the first year of follow-up and 0.39 in the second year. The most frequent reason for hospital admission was CHF in 33% of cases, ventricular arrhythmia in 24%, AF with/without ICD therapy in 14% and IHD in 11%. Only NYHA functional classes III and IV were associated with significantly shorter time to the first cardiac-related rehospitalisation and were an independent predicting factor of these readmissions. This phenomenon was not seen in the case of arrhythmia-related admissions [13].

In another study, Korte et al. demonstrated 156 hospitalisations of 79 (44%) patients among 180 patients after ICD implantation. Mean follow-up time was 25±18 months. Hospital readmission rate per patient during total follow-up was 0.87 and within one patient-year- 0.46. The latter was 0.38 if calculated only for cardiac rehospitalisations. Mean time from discharge to the first arrhythmia-related hospitalisation was 12±9 months, whereas for other cardiac reasons it was 20±16 months. Most patients were admitted because of ventricular rhythm disturbances with adequate ICD therapy - 26% of all rehospitalisations, battery depletion - 19%, device and electrode-related complications - 14% and CHF - 8%. No predicting factors of early hospital readmission were revealed. Age above 60 years was an independent risk factor for prolonged arrhythmia-related and other cardiac hospitalisations [14].

An analysis carried out by Valenti et al., comparing the rate and time of hospitalisations in the year before and the year after ICD implantation, demonstrated that the annual number of admissions was 3.28±2.38 per patient prior to and 0.88±1.23 per patient after the procedure. Most hospitalisations were associated with cardiac disorders, up to 90% after ICD implantation. The predominant cause was ventricular arrhythmias before, and battery depletion after ICD implantation [15].

In the CASCADE trial, the index of all rehospitalisations per patient-year was 0.75 for patients having implanted a first generation ICD device [16].

Rehospitalisation reasons and prevention

The main reasons for our patient hospitalisations were ventricular rhythm disturbances with adequate ICD shock (29.9% - rate similar to previous reports) and CHF (21%). In the examined period we did not have access to the ablation technique for postinfarction ventricular tachycardia and this group was the most numerous. As expected, the risk of non-arrhythmia related hospitalisations was high because most of our patients were predisposed to recurrence of ischaemic events or CHF exacerbation. In our study inadequate therapy with ICD caused only 1% of hospital readmissions and forced premature device exchange just in one case. Eight percent of rehospitalisations were caused by the necessity of ICD replacement after a mean period of 24±16 months. It is likely that technological progress will significantly prolong this time. Most cases of electrode dislocations were diagnosed during primary hospitalisation; thus electrode-related complications were responsible for only 1% of rehospitalisations. Unfortunately, we observed a rather high number of hospitalisations (6%) related to device-associated complications, although a similar rate was observed by Korte et al. (6%) and Fahy et al. (5%) [13, 14]. The future will show whether a reduction in device size and improvements in implantation technique diminish the aforementioned problems.

Risk predicting factors

We found that male patients, those with LVEF below 30% and those in NYHA functional class III were readmitted significantly more often for non-arrhythmia-related although cardiac reasons. None of the examined clinical variables (age, gender, NYHA functional class, ischaemic heart disease, LVEF) were associated with shorter period from discharge to the first cardiac- or arrhythmia-related rehospitalisation. In a study published by Fahy et al. involving fewer patients (n=65) it was shown that NYHA functional classes III and IV were independent predictors of cardiac hospital readmission, although in our study it was not a predicting risk factor for arrhythmia-related rehospitalisation. The study of Korte et al. involving
a larger population (180 patients) did not demonstrate any risk factor of shorter time from discharge to first readmission.

In our study, low LVEF (<30%) was a significant risk factor of cardiac but arrhythmia-unrelated hospital readmissions. Low LVEF usually corresponds to worse functional NYHA class.

Finding of predictors of arrhythmia-related hospitalisations would be of paramount clinical importance. Thus there is a need for further investigations with more studied individuals and longer time of follow-up.

Study limitations
Our study was single institutional, so a relatively low number of patients was enrolled. An additional limitation might be different hospitalisation criteria in the various hospitals. Thirty-five percent of recorded rehospitalisations were in regional hospitals with limited experience with ICD patients.

Conclusions
Despite technological improvements and increased clinical experience, hospital readmissions after ICD implantation are still a frequent phenomenon. The main causes are ventricular rhythm disturbances with adequate ICD therapy and CHF. Low LVEF may predict hospitalisations unrelated to arrhythmia.

References
Ponowne hospitalizacje pacjentów z implantowanym kardiowerterm-defibrylatorem serca

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Streszczenie

Wstęp: Rehospitalizacje są jednym z istotnych problemów u chorych ze wszczepionym kardiowerterm-defibrylatorem (implantable cardioverter defibrillator, ICD). Dokładna analiza przyczyn rehospitalizacji może wpływać na poprawę postępowania u chorych z ICD i ograniczyć ich liczbę.

Cel: Prospektywna analiza częstości, przyczyn i czasu do pierwszej rehospitalizacji chorych po implantacji kardiowertera-defibrylatora (ICD). Poszukiwano również czynników predysponujących do ich wystąpienia.

Metodyka: Analizą objęto 133 kolejnych chorych, którym wszczepiono ICD w Klinice Kardiologii PAM. Przyczyny rehospitalizacji podzielono na kardiologiczne i niekardiologiczne. Obliczono współczynnik rehospitalizacji oraz zbadano, które parametry miały niezależny wpływ na konieczność rehospitalizacji.

 Wyniki: Zaobserwowano 167 ponownych hospitalizacji u 72 (54%) pacjentów po średnio 22±15 mies. Współczynnik rehospitalizacji przypadający na pacjenta podczas całego okresu obserwacji wyniósł 1,26, natomiast podczas roku 0,69. U 42 (32%) pacjentów wystąpiło 91 (54,5%) ponownych przyjęć do szpitala z powodów związanych z arytmią. U 34 (25,6%) chorych stwierdzono 54 (32,3%) rehospitalizacji niezwiązanych z arytmią, a 20 (15%) pacjentów hospitalizowano z przyczyn niekardiologicznych. Średni czas do wystąpienia pierwszej hospitalizacji wyniósł 9±9 mies. Głównymi powodami, z których pacjentów przyjmowano do szpitala, były arytmie komorowe i niewydolność serca. Ustalono, iż pacjenci z frakcją wyrzutową lewej komory (LVEF) poniżej 30% oraz z dolegliwościami w III klasie NYHA byli częściej hospitalizowani z przyczyn niezwiązanych z arytmią.

Wnioski: Hospitalizacje z przyczyn kardiologicznych u pacjentów po implantacji ICD są nadal częstym zjawiskiem. Większość z nich jest spowodowana arytmiami komorowymi oraz niewydolnością serca. Niska LVEF (<30%) i klasa NYHA ≥III są czynnikami predysponującymi do hospitalizacji niezwiązanych z arytmią.

Słowa kluczowe: kardiowerter-defibrylator, rehospitalizacja, czynniki predysponujące

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