

Over 10 years with an implantable cardioverter-defibrillator — a long term follow-up of 60 patients

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Abstract

Background: Transvenous implantable cardioverter-defibrillators (ICD) have been implanted in Poland since 1995. As the method spreads it is important to consider its long-term benefits and disadvantages.

Aim: To assess survival, efficacy and complication rate in ICD patients, who received the device more than ten years earlier.

Methods: Retrospective analysis of 60 ICD patients implanted between 1995–1999.

Results: There were 42 (70%) males, mean age 50.6 ± 16.4 years. In 59 patients ICD was implanted for sudden cardiac death (SCD) secondary prevention. Thirty eight patients (34 M, 63.3%) had coronary artery disease (CAD). The CAD was diagnosed in 89.5% of males and 10.5% of females ($p < 0.0001$). Mean follow-up time was 75.4 ± 34.7 months. During this time 22 patients died (37%, 19 M, 3 F). Three deaths were SCD. Mean one-year mortality was 6.7%. Deaths were more frequent among males: 45.2% vs 16.7%, $p < 0.005$. In CAD mortality was higher than in non-CAD patients (50% vs 13.6%, $p < 0.005$). Appropriate ICD discharges in the ventricular fibrillation (VF) zone occurred in 35 (58%) patients, and in ventricular tachycardia (VT) zone — in 26 (43%) patients. Mean intervention rate per year was 3.7 for VF and 0.6 for VT. Complications occurred in 27 (45%) patients and 5 (8%) of them had no ICD intervention during follow-up. In 5 patients more than one complication was diagnosed. There were inappropriate discharges in 15 (25%) patients, 11 (18%) had electrical storm, and ICD-related infections were noted in 3 (5%) patients. During the perioperative period, lead revisions were done in 4 patients; in 3 with discharges induced by T-wave oversensing and in one with lead dislocation. Four cases of lead failure occurred during follow-up, requiring new lead implantation. In 4 patients, electrical storm (3 patients) and supraventricular tachycardia with ICD discharges (1 patient) were treated with radiofrequency ablation. Only 10 (17%) patients did not demonstrate any ICD interventions or ICD-related complications.

Conclusions: 1. ICD interventions caused by malignant ventricular arrhythmias occurred in 75% patients with the device implanted more than 10 years earlier. 2. Almost a half of the analysed population suffered from complications and side effects related to implanted ICD and they were present in 8% of subjects without ICD intervention. Neither ICD interventions nor device-related adverse events were recorded in 17% of patients.

Key words: implantable cardioverter-defibrillator, long-term observation, survival, appropriate and inappropriate interventions, complications

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INTRODUCTION

It has been slightly more than 20 years since the first implantable cardioverter-defibrillator (ICD) with epicardial leads has been implanted in Poland, in Katowice-Ochojec [1]. The era

of transvenous ICD implantation began in our country in 1995, in three centres: Gdansk, Katowice and Warsaw. Currently in Poland there are about 60 centres, in which over 80 ICDs are implanted per million inhabitants. This method, used for pri-

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Table 1. Characteristics of patients selected for ICD therapy by aetiology

Parametr	Non-CAD	CAD	P
Aetiology	22 (36.7%) DCM: 6, HCM: 3, LQTS: 3, PVF: 9, ToF: 1	38 (63.3%)	
Indications			
Ventricular fibrillation	19 (86.4%)	11 (29.0%)	< 0.0001
Ventricular tachycardia	3 (13.6%)	26 (68.4%)	
Primary prevention of SCD	0	1 (2.6%)	
NYHA class	1.4 ± 0.7	2.1 ± 0.3	< 0.0001
LVEF [%]	50.8 ± 14.2	32.8 ± 4.6	< 0.0001

CAD — coronary artery disease; DCM — dilated cardiomyopathy; HCM — hypertrophic cardiomyopathy; LQTS — long QT syndrome; PVF — primary ventricular fibrillation; ToF — tetralogy of Fallot (corrected); SCD — sudden cardiac death; NYHA — New York Heart Association; LVEF — left ventricular ejection fraction

mary as well as secondary prevention, is currently recommended in a wide population of patients with appropriately defined risk of sudden cardiac death (SCD) [4]. It is known that ICD implantation significantly prolongs life, but at the same time it poses new problems related to long-term treatment effects [5–10]. These aspects should be taken into consideration with respect to increasing availability of such therapy.

The aim of the study was a single-centre, long-term follow-up analysis of survival, efficacy and complication rate in ICD patients, who had received their first device at least ten years earlier.

METHODS

Sixty consecutive patients with ICD implanted at least 10 years earlier were included (all the implantations were done between 1995 and 1999). Mortality rates and appropriate ICD interventions with emphasis on discharges in the ventricular fibrillation (VF) zone were analysed. Complications and re-operations were studied, as well as long-term issues requiring invasive and non-invasive intervention. The date of the last contact with a living patient or the date of death were assumed end-points of the follow-up. Complete data of all the patients up to the study end-point were available.

Statistical methods

Statistical analysis was performed using SAS 9.2 statistical package. Null hypotheses were verified at the statistical significance level of 0.05. For assessment of between-group differences of mean values Student t test was used, provided homogeneity of variance and normal distribution of continuous variables had been confirmed. Results are expressed as means and standard deviations. Categorical data were analysed with χ^2 test with Yates correction or with exact Fisher test. Kaplan-Meier survival curves were plotted and hazard ratios in 3-month periods were estimated for survival probability assessment.

RESULTS

There were 42 men (M, 70%) and 18 women (F, 30%) aged 50.6 ± 16.4 years. Mean age of women was lower than that of men: 40.9 ± 17.4 vs 54.6 ± 14.4 ($p < 0.005$). In 59 patients ICD was implanted for secondary prevention. In one patient the indication for ICD was primary post-infarction prophylaxis of SCD. In 38 (63.3%) patients (34 M, 4 F) coronary artery disease (CAD) was diagnosed and in 22 patients (8 M, 14 F) a non-coronary aetiology (non-CAD) was established. The CAD was diagnosed in as much as 89.5% of men and in only 10.5% of women ($p = 0.0001$). Clinical characteristics of the study group is presented in Table 1. Mean follow-up to the end-point was 75.4 ± 34.7 months.

Mortality

In the study group 22 deaths were recorded (37%, 19 M, 3 F). The deaths were related to higher NYHA class (2.2 ± 0.5 vs 1.7 ± 0.6 , $p = 0.0007$) and lower left ventricular ejection fraction (LVEF) (33.0 ± 7.5 vs $43.1 \pm 13.6\%$, $p = 0.0005$). Average mortality rate during the first year after implantation was 6.7%. Sixteen subjects died from heart failure progression, including 1 patient with heart transplant which was performed one year after ICD implantation. Deaths were sudden in 3 patients. In 2 patients extracardiac cause of death was established. In 1 patient, the mechanism of death could not be determined. Deaths were significantly more frequent in men than in women: 45.2% vs 16.7% ($p < 0.005$). In the CAD patients, mortality was higher than in the non-CAD group: 50% vs 13.6% ($p < 0.005$), and this difference remained significant in women: 50% vs 7% ($p < 0.05$). Although in the group of men with CAD the mortality rate was also 50%, no significant difference was found vs non-CAD males, in whom mortality was 25% (Fig. 1).

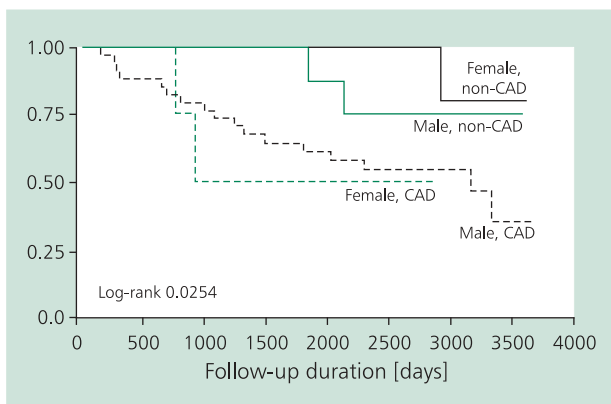


Figure 1. Cumulative survival probability

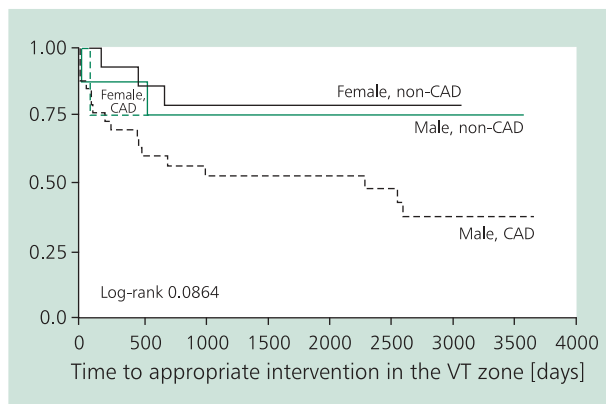


Figure 3. Cumulative survival probability without appropriate intervention in the ventricular tachycardia (VT) zone

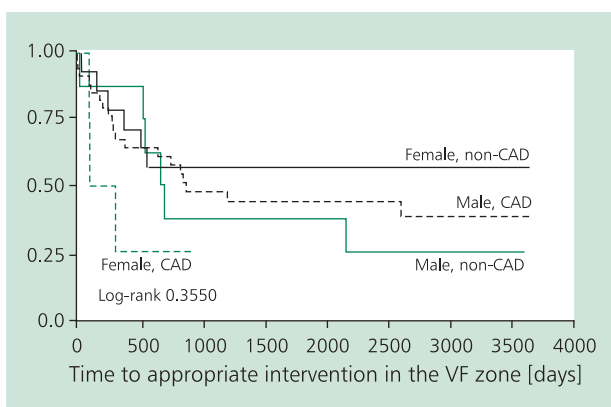


Figure 2. Cumulative survival probability without appropriate intervention in the ventricular fibrillation (VF) zone

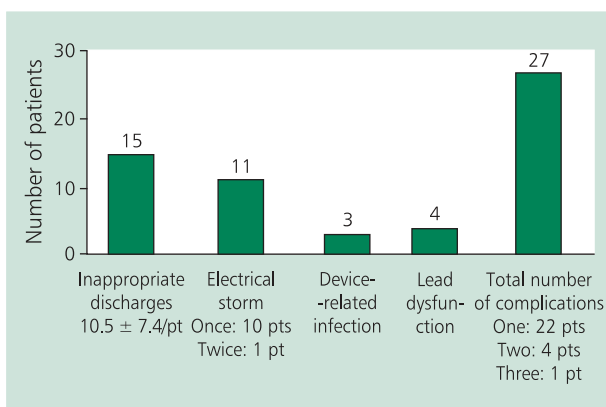


Figure 4. The number of patients with inappropriate shocks and adverse events

Appropriate ICD interventions

Successful interventions within the VF zone were recorded in 35 (58%) patients, in the ventricular tachycardia (VT) zone in 26 (43%) patients and in both zones — in 16 (27%). At least one appropriate intervention occurred in 45 (75%) patients. Detailed numbers of interventions in each subgroup are presented in Table 2, and the risk of each type of arrhythmia in subgroups — in Figures 2 and 3. Mean number of appropriate interventions per year of follow-up was 3.7 for VF and 0.6 for VT.

Complications and adverse events

Complications occurred in a total of 27 (45%) patients, including 5 (8%) patients in whom no therapy from the device was recorded: in 4 persons two different types of complications were noted, in 1 person — three types of complications occurred (Fig. 4). In 15 (25%) patients inappropriate discharges were recorded (Table 3). Device-related infections occurred in 3 (5%) patients; all three in patients after at least two device reimplantations. In 1 of these patients, infective en-

Table 2. Number and percentage of patients with therapies in ventricular fibrillation (VF) and ventricular tachycardia (VT) zones, in subgroups

	N	VF	VT	VT or VF
Males; CAD	34	20 (58.8%)	20 (58.8%)	27 (79.4%)
Males; non-CAD	8	6 (75%)	2 (25%)	6 (75%)
Females; CAD+	4	3 (75%)	1 (25%)	3 (75%)
Females; non-CAD	14	6 (42.9%)	3 (21.4%)	9 (64.3%)

Table 3. Causes of inappropriate shocks of ICD

Cause of inappropriate shock	Patients
T-wave oversensing	5
Sinus tachycardia	3
Atrial fibrillation	6
Lead dysfunction	1
Electromagnetic interference	1
Total	15*

*Two independent causes in 1 patient

docarditis was detected, and in 2 others, infection was localised and they were treated conservatively. Lead dysfunction occurred in 4 patients. In 1 of them this was the cause of inappropriate discharges. In 11 (18%) of patients electrical storm occurred, defined as ≥ 3 appropriate discharges in 24 hours. The complications led to hospital admission in all these patients, and 11 patients were hospitalised more than once. Duration of hospital stay ranged from 2 to 10 days.

Reinterventions and elective procedures

In the periprocedural period after first implantation, 4 lead repositions were performed — in 3 patients to prevent inappropriate discharges due to T wave oversensing and in 1 patient due to lead dislocation.

In all patients with lead dysfunction (4 persons) new leads were implanted; in 1 patient simultaneous percutaneous extraction of the dysfunctional lead was done. One subject with device-related infection was treated by complete surgical removal of the leads and the generator, and subsequently new system was implanted. In the 3 patients with electrical storm (1 M with CAD, 2 F without CAD), radiofrequency (RF) ablation of arrhythmogenic substrate was performed. In 1 patient in whom inappropriate discharges were due to atrial fibrillation with fast ventricular rates, atrioventricular junction ablation was performed.

In 8 (13%) patients, first ICD implantation was abdominal. In 44 (73%) patients at least one reimplantation was performed, including 14 patients with two and 5 patients with three reimplantations. Out of these, 10 (14.7%) reoperations were performed as urgent procedures recommended by the manufacturer due to product dysfunction. At the time of reimplantation in 1 patient single chamber ICD was replaced with a system with DDD pacing capabilities.

During follow-up in 10 (17%) patients (6 CAD, 4 non-CAD) no clinical events were noted — neither discharge therapy nor complications/adverse events, with exception of elective reimplantation procedures.

DISCUSSION

Out of presented results of over 10-year follow-up of patients with implanted ICD, most noticeable are the following: 37%

total mortality, appropriate interventions in 75% and complications and adverse effects in 47% of the patients.

Mortality rates of patients with indications for ICD treatment that were recommended in the years 1995–1999 were different from these rates in the more numerous contemporary population of ICD patients [5, 6, 11]. The ICD therapy was hardly available during its first years and it was limited to highly selected secondary prophylaxis patients, chiefly patients with history of myocardial infarction (MI) and advanced heart failure, what resulted in high baseline risk of mortality. However, and it seems interesting, in the long term follow-up of MADIT II population, in which ICD was used only in primary SCD prevention, first-year mortality was higher than observed in the study group: 8.5% vs 6.7% [12]. This may be related to post-infarction LV dysfunction and LVEF $\leq 30\%$ in all the MADIT II patients; in our group, part of the patients were implanted due to primary VF and no structural heart disease was present, hence the prognosis was markedly improved.

The observed mortality rate in the study population can be influenced by the fact that up to the beginning of the current decade, ICDs with resynchronisation function (CRT-D) were not available in Poland. These devices would have possibly changed clinical course of at least some of the heart failure patients with intraventricular conduction disturbances and markedly reduced LVEF. In the study group, no instances of ICD upgrade to CRT-D were recorded, what could have resulted from the fact that potential candidates for such treatment had died before the method was introduced.

Irrespective of gender, 50% of CAD patients died within 10–14 years; all had a history of MI and malignant ventricular arrhythmia. In the nineties, the majority of these patients could not be treated by direct coronary intervention. The vast majority of these patients died of end-stage heart failure, which was a consequence of the natural course of CAD, and of conservatively treated MI [13–15]. The lowest mortality was noted in the subgroup of women without CAD. This subgroup, consisting of 14 persons, clearly lowered the mean age of females with ICD in our study.

Sudden deaths in ICD patients merit separate address. In our study, 3 deaths of such mechanism were recorded. These deaths can be attributed to non-arrhythmic cardiac causes, such as electromechanical dissociation in the course of heart failure or pulmonary embolism, as well as to large stroke, ineffective defibrillation and lead or ICD failure. Equipment recalls, despite technology progress, are inevitable part of the care of patients with implantable devices [16]. It should also be kept in mind and warned, that human error is also possible, due to which VF zone can be inappropriately programmed or not programmed at all.

An ICD that had been implanted in one of the sudden death patients was found on the manufacturer's list of potentially malfunctioning devices. In such cases, ultimate diagnosis could have been made after post mortem ICD memory reading, but due to ethical and logistic reasons it was impracticable.

Appropriate ICD interventions. Unequivocal interpretation of arrhythmia that was interrupted by the device is difficult. In the VF zone, which is commonly set at ventricular rates above 200–240/min, fast, potentially self-terminating arrhythmias can occur, as well as relatively mildly symptomatic arrhythmias. Despite these objections, appropriate interventions within the VF zone should be considered a proof of emergent prevention of sudden arrhythmic death [17] and such a situation occurred in as much as 58% of our patients. Direct relevance of therapy applied in the VT zone (usually 160–200/min) can be even more unequivocal, although within these rates, arrhythmic events that are directly life-threatening can also occur. In long-term studies (up to 4 years) on the secondary SCD prevention, intervention rates within VF or VT zones of up to 70% were reported [18–20]. The rates of appropriate interventions in our study were comparable, although they reflect a much longer follow-up period. It may be explained by the fact that the greatest probability of appropriate intervention occurs within the first 2 years from ICD implantation and that it diminishes over time (what was also confirmed in our study). It should be underlined that appropriate ICD interventions — even anti-tachycardia pacing — that prevent the emergent consequences of malignant arrhythmia, are markers of adverse long-term prognosis [21].

Complications. The significant impact that serious adverse effects and complications of ICD treatment have on quality of life is widely recognised [22, 23]. Nearly a half of our patients experienced either of these events, and all of them required hospital admission. The most frequent complication was inappropriate ICD discharge, recorded in 25% of the patients, with a mean incidence of 10 events per person. At present, this percentage is much lower and this should be attributed to the upgraded detection algorithms used in contemporary devices [24]. In the majority of patients treated in the initial years of the study period single chamber (i.e. ventricular) ICDs were the only available devices. In the study group, the incidence of electrical storm reflected respective rates in the available literature or was even slightly less frequent [25, 26]. It should be underlined that in 3 of these patients catheter ablation was then performed, and it is the method of treatment that has been increasingly recommended [4, 27]

To our surprise, only 4 cases of lead dysfunction were recorded in the study period of over 10 years. According to Kleemann et al. [28], yearly risk of such complication over a comparable study period was gradually increasing each year, from 2% to as much as 20%. It is possible that some of these events were clinically silent in our study group and thus remained undetected until the death of these patients, and thus their potential clinical relevance is undetermined. Moreover, the leads that were used in Poland at the time could have

differed in diameter from the leads used in western countries. Protective influence of greater lead diameter on complication rates is now one of the commonly discussed issues [29].

Device infections were detected in 3 (5%) patients. All 3 occurred in the subgroup of 8 patients in whom first implantation was abdominal and who underwent at least 2 subsequent reimplantations during follow-up. In 1 case, cardiac surgery for complete system removal was warranted. According to literature, infection rates do not exceed 2–5% in large groups [30, 31]. In our small group of patients treated during the initial period of implementation of this treatment method, we were dealing with the learning curve phenomenon, long-lasting multi-operator procedures, two incisions and indirect defibrillation testing before suturing the operation site. These features, along with subsequent reimplantations, are clearly the factors promoting implantable device infection [32].

Elective reimplantation procedures. The ICD battery life is much shorter than that of a pacemaker and even today, it does not exceed 5–6 years [33]. Hence, in 5 patients we provide follow-up to their 4th device and in the entire study group 68 ICD reimplantations were performed. Reimplantations are usually elective procedures and these are the majority of reinterventions. However, the issue of urgent guarantee reimplantations — currently decreasing — is still a significant component of ICD patient care [29]. Due to the evolution of ICD technology and implantation techniques (from abdominal to submuscular and finally subfascial implants), at present these procedures are relatively short and simple. It should be kept in mind though, that every reintervention brings about inherent risk of infection and system damage. As much as 26% patients had not survived to the time of their first reimplantation, what confirms once again that the mortality of patients with significant cardiovascular morbidity is high irrespective of treatment.

Lastly, only 1 person had the ICD implanted for primary SCD prevention. Thus, our analysis is practically confined to patients selected for ICD implantation due to persistent, malignant ventricular arrhythmia. However, nowadays, it is primary prevention that became the predominant indication for ICD implantation worldwide, and it currently exceeds 80% of indications for these procedures [34].

CONCLUSIONS

1. In the study group of patients with ICD implanted over 10 years earlier, 75% of patients experienced appropriate therapy for malignant ventricular arrhythmia.
2. In this population, complications and adverse events of ICD therapy were observed in nearly a half of the patients, including 8% of patients in whom no device intervention was recorded. In 17% of the patients, neither interventions nor adverse events of the therapy were observed.

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Ponad 10 lat ze wszczepialnym kardiowerterem-defibrylatorem — obserwacja odległa 60 chorych

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Streszczenie

Wstęp: Historia przeżytych wszczepialnych kardiowerterów-defibrylatorów (ICD) w Polsce sięga 15 lat. W związku z coraz większą powszechnością ICD korzyści i komplikacje tej metody są istotne i coraz lepiej poznane dzięki wieloletnim obserwacjom chorych.

Cel: Celem pracy była analiza obserwacyjna przeżywalności, skuteczności i powikłań metody u chorych leczonych ICD w okresie co najmniej 10-letnim.

Metody: Analizie poddano 60 pacjentów z ICD wszczepionym w latach 1995–1999.

Wyniki: W badanej grupie było 42 mężczyzn (70% M) i 18 kobiet (30% K) w wieku $50,6 \pm 16,4$ roku. U 59 osób ICD wszczepiono w ramach profilaktyki wtórnej nagłego zgonu sercowego (SCD). U 38 (63,3%) pacjentów (34 M, 4 K) stwierdzono chorobę wieńcową (CAD); pozostali chorzy byli bez CAD (non-CAD). Choroba wieńcowa występowała u 89,5% M i u 10,5% K ($p < 0,0001$). Średni czas obserwacji wynosił $75,4 \pm 34,7$ miesiąca. W obserwowanej grupie zmarło 22 chorych (37%; 19M, 3K). Śmiertelność w pierwszym roku obserwacji wyniosła 6,7%. U 3 chorych zgon miał charakter nagły. Zgony występowały znamienne częściej u mężczyzn niż u kobiet: 45,2% v. 16,7% ($p < 0,005$). W grupie chorych z CAD śmiertelność była większa niż u pozostałych: 50% v. 13,6% ($p < 0,005$). Skuteczne interwencje w strefie migotania komór (VF) wystąpiły u 35 (58%) chorych, a w strefie częstoskurczu komorowego (VT) — u 26 (43%) osób. Średnia interwencji na rok obserwacji wynosiła 3,7 dla VF i 0,6 dla VT. Powikłania wystąpiły łącznie u 27 (45%) osób, w tym u 5 (8%) pacjentów, u których nie wystąpiły interwencje ICD. U 4 osób zanotowano dwa różne rodzaje powikłań, u 1 osoby — trzy różne rodzaje. U 15 (25%) chorych wystąpiły nieadekwatne wyładowania, u 11 (18%) pacjentów — burza elektryczna. Infekcje ICD stwierdzono u 3 (5%) osób. W okresie okołozabiegowym po pierwszorazowym wszczępieniu wykonano 4 repozycje elektrod — u 3 chorych w celu zapobieżenia nieadekwatnym wyładowaniom z powodu nadczułości załamka T oraz u 1 chorego z dyslokacją elektrody. U 4 chorych z uszkodzeniem elektrod wszczepiono nowe elektrody. U 4 chorych z epizodem burzy elektrycznej lub nieadekwatnymi wyładowaniami ICD (1 M CAD, 1 M non-CAD, 2 K non-CAD) wykonano ablację podłoża arytmii prądem o wysokiej częstotliwości. W trakcie obserwacji u 10 chorych (17%; 6 CAD, 4 non-CAD) nie zanotowano żadnego incydentu klinicznego — ani terapii ze wszczepionego urządzenia, ani powikłania lub działania niepożądanego, z wyłączeniem planowych wymian ICD.

Wnioski: 1. Spośród osób z automatycznym ICD wszczepionym ponad 10 lat wcześniej 75% chorych doświadczyło adekwatnej terapii złośliwej arytmii komorowej. 2. W obserwowanej populacji powikłania i działania niepożądane terapii za pomocą ICD dotyczyły prawie 50% chorych, z czego u 8% powikłania wystąpiły u osób bez interwencji urządzenia. U 17% pacjentów nie wystąpiły ani interwencje, ani efekty niepożądane stosowanej metody.

Słowa kluczowe: wszczepialny kardiowerter-defibrylator, obserwacja długoterminowa, przeżywalność, adekwatne i nieadekwatne interwencje, powikłania

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