

Changing trends in the use of cardiac implantable electronic devices over 14 years of practice at a cardiology reference center

Trendy zmian rodzajów stosowanych kardiologicznych wszczepialnych urządzeń elektronicznych z perspektywy 14-letniego okresu wykonywania procedur w referencyjnym ośrodku kardiologicznym

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Abstract

Introduction. Indications for the use of cardiac implantable electronic devices (CIEDs) have been expanded over the years, just as there has been progress in CIED technology. Open cardiothoracic surgeries have been replaced by transvenous procedures conducted with only local anesthesia. These factors have effected certain changes in the quantity, proportions, and types of implanted devices. However, it takes a long observation period to determine the direction, duration, or rapidity of such trend changes as well as to project the relevant figures for the future.

Material and methods. This retrospective analysis included CIED implantation procedures performed at our center in the period from 2002 to 2015. The analyses were based on medical records, including: procedure logs, procedure reports, and outpatient follow-up entries. This manuscript includes a year-by-year analysis of selected types of CIED-related procedures, i.e.: *de novo* device implantation, device replacement, and device upgrade procedures.

Results. A total of 7,921 CIED-related procedures were conducted in the evaluated period. Female patients constituted 52% and males 48% (mean age 72.7 years). *De novo* device implantation procedures constituted 68.5% of all CIED-related procedures, device replacement due to predicted battery depletion was conducted in 24.4% of cases, and the remaining 7.1% of procedures were classified as 'other'. The *de novo* device implantation group involved pacemaker (PM) implantation procedures (81.7%) including single-chamber atrial (AAI) (6.2%) and ventricular (VVI) (49.6%) devices and dual-chamber atrioventricular (DDD) (43.8%) devices. The remaining 18.3% of the *de novo* procedures were implantable cardioverter-defibrillators (ICD) (83.2%) including dual (ICD-DR) (26.0%) and single-chamber (ICD-VR) (57.2%) devices and cardiac resynchronization therapy defibrillators (CRT-D) (16.7%). Single-chamber to dual-chamber pacemaker replacement procedures constituted 82.4% of all CIED upgrade procedures. The remaining 17.6% of device upgrade procedures included adding new functions, such as terminating ventricular tachyarrhythmias (upgrade to ICD) and/or cardiac resynchronization (upgrade to CRT-D).

Conclusions. The general rise in the number of CIED-related procedures saw increasing proportions of ICD and CRT device use both in the *de novo* device implantation and device upgrade groups. Our projections indicate a persistent trend of increasing number of CIED-related procedures discussed in this manuscript.

Key words: implantable cardioverter-defibrillators, cardiac pacemakers, retrospective study

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Introduction

Over the years, indications for the use of cardiac implantable electronic devices (CIEDs) have been gradually expanded: from pacemakers (PMs) for the treatment of bradyarrhythmias only, through implantable cardioverter-defibrillators (ICDs) designed to prevent sudden cardiac death (SCD) due to life-threatening arrhythmias, to cardiac resynchronization therapy (CRT) devices for improving systolic function. From the time of the earliest procedures, the CIEDs (PMs; ICDs) and their components (leads) also underwent technological evolution [1–4].

The early, open cardiothoracic procedures with epicardial lead placement evolved towards much less invasive procedures with transvenous cardiac lead insertion, which require only local anesthesia. The established technique used to introduce cardiac leads into the venous lumen via dissection and cut-down of either a cephalic (CV) or jugular vein was expanded to include axillary vein (AV) or subclavian vein (SV) puncture with special lead introducer kits [5–7].

Progressive sinus node and/or atrioventricular node dysfunction and/or development of left ventricular systolic asynchrony calls for an upgrade in CIED functions. This requires a re-intervention to introduce additional leads and replace the device with a new one, equipped to manage cardiac dysfunction [8, 9].

The expanded indications for CIED implantation, reduced procedure invasiveness, and emergence of new device implantation centers have led to increasing numbers of CIED-related procedures, also in Poland [10–12].

All these factors effect changes in proportions of implanted CIEDs; however, the direction, duration, and rapidity of the emerging trends can be observed only over longer periods of time. This aspect of chronic electrotherapy prompted us to analyze CIED implantation data in our center over a 14-year period.

The objective of this study was to analyze the trends in the changes of the CIED types used in a cardiology reference center over a 14-year period.

Material and methods

The study was a retrospective analysis of CIED-related procedures (stratified by groups listed below) performed at our cardiology center between the year 2002 and 2015.

We analyzed the data found in medical records: procedure logs, procedure reports, and follow-up examination entries with a particular focus on: patient characteristics (age, sex), date and nature of the procedure, and the CIED involved.

For the purpose of this manuscript we defined the evaluated procedures as follows:

- device implantation – *de novo* CIED implantation with transvenous cardiac lead insertion;

- device replacement – elective replacement of the CIED (PM, ICD) at the stage of approaching battery depletion (elective replacement indicator, ERI);
- device upgrade – CIED replacement with a device with an additional lead to upgrade the function of the previous system.

Statistical analyses

The classic method of least squares was used to estimate the trend model for the number of procedures performed in the period of 2002–2015. The total statistical significance of the estimated trend model was calculated with the F-test in the analysis of variance and the significance of the individual parameters – with Student's *t*-test (including the rate of change). The residuals in the estimated trend model met the requirements of the classic least squares method. Student's *t*-test was used to calculate the statistical significance of the difference in means. The *p*-values of < 0.05 were considered statistically significant. The Bonferroni correction for *p*-values was used for multiple comparisons. For more clarity in the observed changes, some figures present the evaluated period divided into three intervals: 2002–2006, 2007–2010, and 2011–2015, inclusively.

Results

In the period from January 1, 2002 to December 31, 2015, there were a total of 7,921 transvenous CIED-related procedures conducted at our center. The proportion of female patients in the evaluated patient population was 53% (vs. 47% of males) (mean patient age 72.7 years). Figure 1 illustrates the quantity of all CIED-related procedures in the evaluated period.

De novo device implantation procedures constituted 68.5% of all CIED-related procedures. Device replacement procedures (dictated by ERI) constituted 24.4% of cases while the remaining 7.1% of procedures involved other procedure types, such as pacing mode change, device removal, etc. Figure 2A shows year-by-year quantitative data for these types of procedures in the analyzed period, with the data-set distribution shown in Figure 2B. The differences between mean numbers of these three types of procedures in the evaluated period were characterized by very low *p*-values ($p < 0.0001$ for all comparisons).

Out of 4,395 *de novo* device implantation procedures those that involved PM implantation constituted 81.7%, including 6.2% of atrial pacing (AAI), 49.6% of ventricular pacing (VVI), and 35% of atrioventricular pacing (DDD) device implantation procedures. The proportion of cardiac pacing device types implanted over the last 14 years has changed. This includes a decrease in single-chamber (VVI-mode) devices (59% → 46% → 41%) in favor of double-chamber (DDD-mode) devices (31% → 49% → 55%).

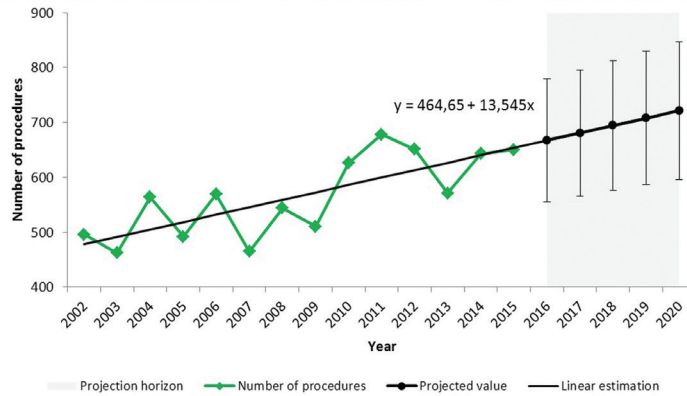


Figure 1. Quantitative distribution of all CIED-related procedures conducted at the center in 2002–2015 along with estimated future figures (with a 95% confidence interval for the predicted values)

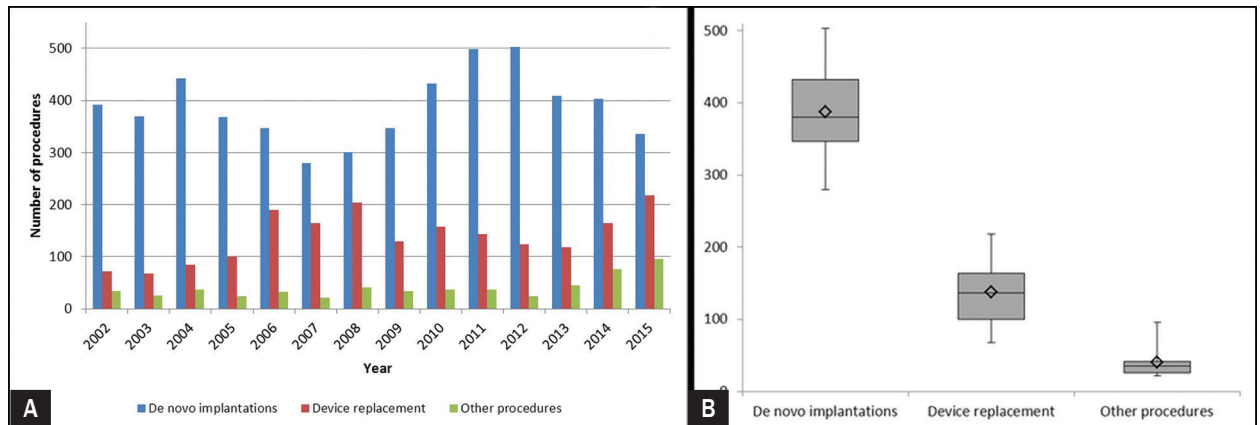


Figure 2A. Quantitative distribution in the three identified procedure subtypes performed in 2002–2015; **B.** Box-plot showing the data-set distribution

Figure 3 illustrates the proportions of these types of procedures in the analyzed period.

There is a substantial qualitative change involving an increase in double-chamber DDD system implantation with the corresponding decrease in AAI and VVI system implantation procedures observed over time. In the subgroup of DDD system implantation procedures the quantitative increases observed in the predetermined intervals were statistically significant, especially in the recent years ($p < 0.0001$). This finding corresponded to a decrease in single-chamber system implantation in the same time periods ($p < 0.0001$ for VVI).

Out of all 990 *de novo* non-PM CIED implantation procedures those involving ICDs constituted 81.7% (including ICD-DR 26.0%, ICD-VR 57.2%) and those involving cardiac resynchronization therapy-defibrillator (CRT-D) devices constituted 16.7%.

The incidences of these types of procedures in the evaluated time periods are presented in Figure 4. The ICD group shows an increase in the numbers of ICD-VR

implantation procedures from those recorded in the period of 2002–2006 to those in 2007–2010 ($p < 0.0366$) as well as from those recorded in 2002–2006 to those in 2011–2015 ($p < 0.0001$).

Irrespective of the consistently considerable proportion of ICD-VR implantation procedures, we observed an increase in dual-chamber ICDs combining ventricular tachyarrhythmia therapy with ventricular and atrial pacing and sensing (ICD-DR), with the p -value < 0.0328 (for 2011–2015 vs. 2002–2006). In the case of CRT-D device implantation procedures the quantitative changes were similar to those observed for ICD-DR devices, with a significant increase in the number of procedures conducted in 2011–2015 vs. those conducted in 2002–2006 ($p < 0.0148$).

As shown in Figure 5, CRT-pacemakers (CRT-P) constituted 66% of the 53 rarely performed procedures involving the implantation of biatrial (BiAAI), biventricular (BiVVI), biatrial/right-ventricle (BiADDD), and left-atrium (1 LAAL system, not illustrated graphically) pacing systems.

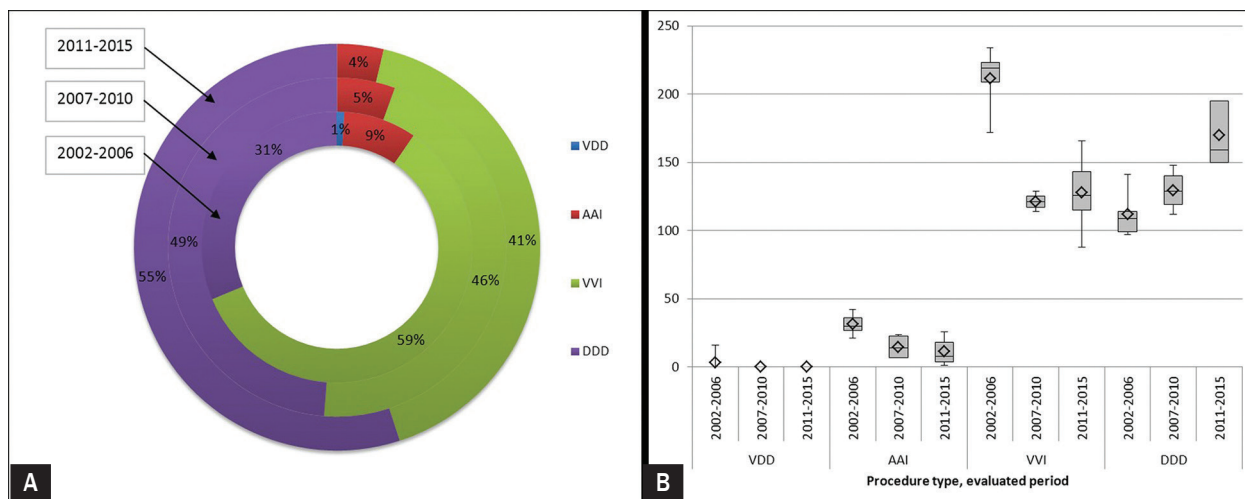


Figure 3A. Quantitative distribution of *de novo* AAI, VVI, DDD, and VDD system implantation procedures in three time periods spanning the evaluated 14-year interval (2002–2015); **B.** Box-plot showing the data-set distribution

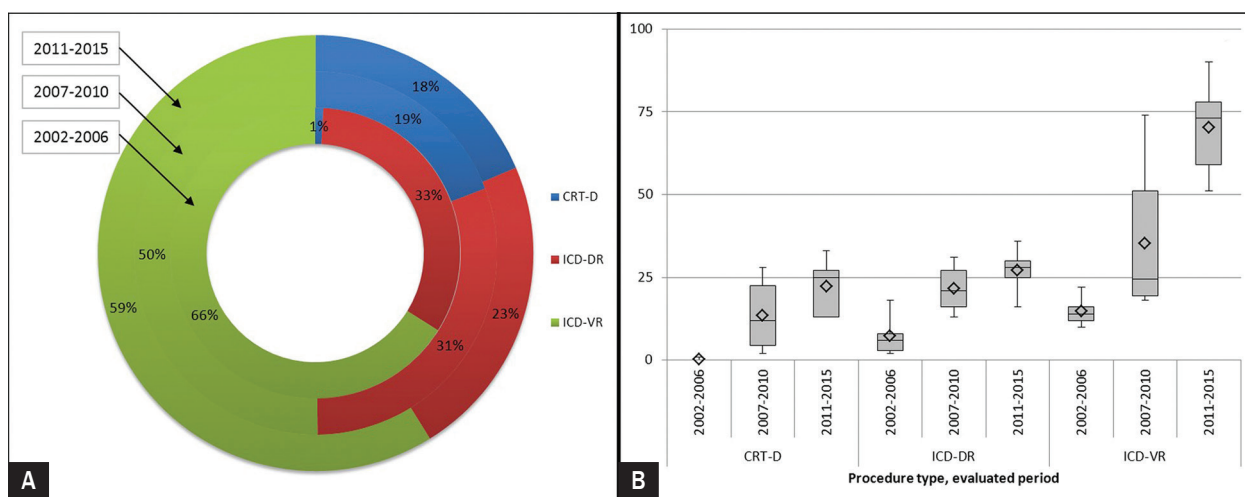


Figure 4A. Quantitative distribution of ICD (ICD-DR, ICD-VR) and CRT-D device implantation procedures in three time periods spanning the evaluated interval (2002–2015); **B.** Box-plot showing the data-set distribution

Lead revision procedures involving new cardiac lead placement without inactive lead extraction, but not involving device replacement, constituted 1% of all analyzed procedures. Indications for these procedures were mechanical damage to the insulation or the conductor wire or increased stimulation threshold. In this type of procedures the original mode of electrotherapy remained unchanged.

PM upgrade procedures (n = 168) constituted 82.4% of all device upgrade procedures. This subtype of device upgrade procedures involved adding a new cardiac lead and replacing the existing pacemaker with one that offered more pacing mode options (Figure 6A).

Device upgrade procedures involving introduction of a system with new functions, such as ventricular arrhythmia termination (ICD device) or cardiac resynchronization (CRT-D) constituted 17.6% of all upgrade procedures. Figure 6B illustrates the marked emergence of device upgrades to ICD-DR and CRT-D.

Discussion

The analyzed 14-year period shows a growing trend in the numbers of CIED-related procedures, which allowed us to predict the projected future figures for procedures of the same type. However, we observed a change in proportions

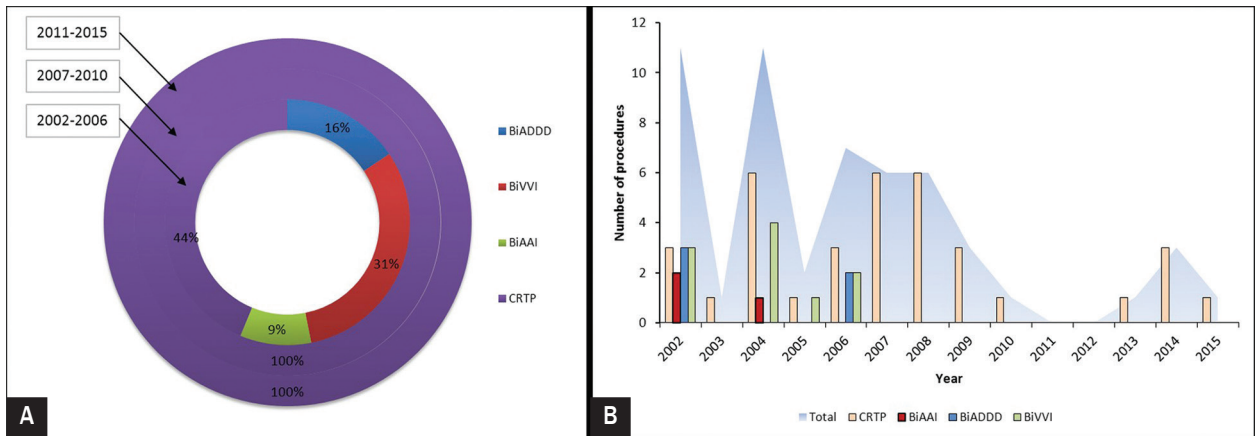


Figure 5A, B. Procedures involving rare pacing systems conducted in 2002–2015

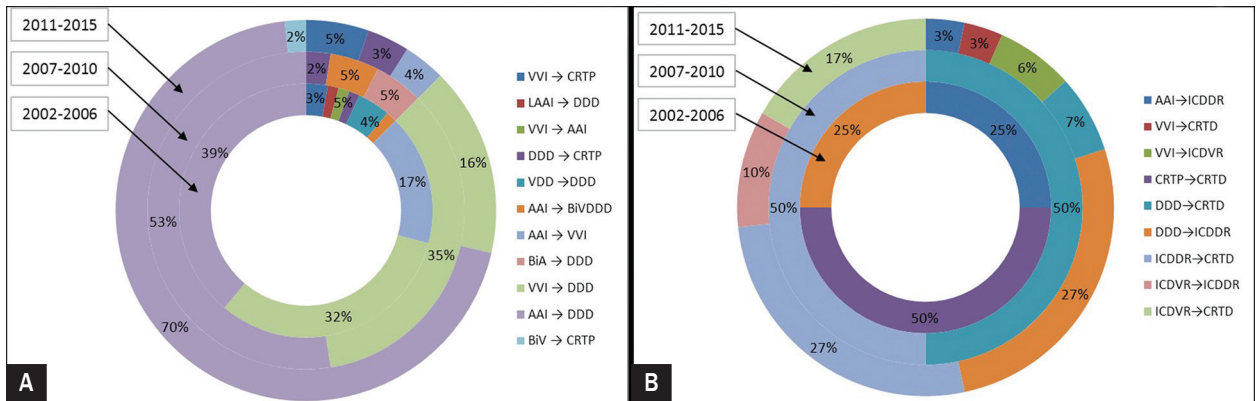


Figure 6A, B. Pacing system upgrade procedures conducted in 2002–2015; B. Pacing system upgrade procedures to ICD or CRT systems conducted in 2002–2015

between the *de novo* device implantation, device replacement (dictated by ERI), and other CIED-related procedures.

The *de novo* device implantation procedures showed pronounced, reverse changes in proportion involving a growing number of dual-chamber atrioventricular (DDD) systems with a simultaneously diminishing number of single-chamber systems. This seems to be associated with the indications for DDD-mode device implantation being followed more accurately (according to the established standards), particularly when it comes to the elderly. Moreover, the introduction of screw-in leads, which ensure a more secure atrial lead placement (as opposed to tined leads), has contributed to higher rates of atrioventricular pacing devices being implanted, even in cases presenting anatomical or electrophysiological challenges.

The surge in the number of device replacement procedures at our center in the recent years seems to be due to an overlap in the ERI phases of two types of devices: PMs (which are characterized by a long battery life) implanted

over 10 years ago and ICDs, with a considerably shorter battery life, implanted several years ago. The last several years saw an increase in ICD implantation procedures.

The steady increase in the number of implanted CRT-D devices, which combine the antiarrhythmic function with left ventricular asynchrony management, was similar to that observed among ICD-DR device implantation procedures. The group of rarely implanted CIED types featured mainly CRT-P devices.

The quantitative decrease in lead revision procedures involving new cardiac lead placement without inactive lead extraction seems to be, at least partly, due to continual technological and material advances.

The majority of PM upgrade procedures involved devices offering atrioventricular block treatment options. These PM replacement procedures with a cardiac lead addition involved either a ventricular lead being added to the already implanted atrial lead in atrial pacing devices (AAI → DDD) as it became indicated by a developed sinus

node dysfunction, or it was an atrial lead (VVI → DDD) that was added due to pacemaker syndrome in patients with pre-existing ventricular pacing.

The device upgrade group demonstrated a noticeably increasing proportion of pacemakers, which offer only a simple pacing function, being replaced with ICD and/or CRT devices. This phenomenon can be linked to the natural heart disease progression involving sinus node dysfunction and/or left ventricular systolic dysfunction in patients already implanted with conventional permanent cardiac pacing devices (typically in their 80 s).

The presented tendencies in qualitative and quantitative changes involving CIED-related procedures are similar to those observed in other centers in Poland and in other countries [10–12].

Conclusions

The analyzed period of time demonstrated an increase in both the general number of CIED-related procedures and

the proportion of ICD and/or CRT devices in *de novo* and upgrade procedures.

The projected future figures suggest continued increase in the number of procedures involving the CIEDs analyzed in this manuscript.

Limitations

One limitation of this study was the fact that the changes in the type and number of implanted CIED were analyzed based on data from procedure reports. Such reference materials introduce a certain number of errors, e.g. altering the indications for implanting a particular device based on the technical feasibility of performing a given procedure.

Nonetheless, considering the long, 14-year, period of observation and the sheer number of total procedures, we do not believe such instances should noticeably affect the presented trends. For similar reasons a detailed analysis of rarely used cardiac electrotherapy devices was not included in this manuscript.

Streszczenie

Wstęp. Wskazania do stosowania kardiologicznych wszczepialnych urządzeń elektronicznych (CIED) przez lata się rozszerzyły, a także dokonała się ewolucja rozwiązań technologicznych implantowanych urządzeń. Operacje torakochirurgiczne ustąpiły miejsca technikom zabiegowym z wykorzystaniem układu żylnego i wykonywanym w tylko miejscowym znieczuleniu. Wszystkie te czynniki łącznie modelują zmianę liczby i proporcji oraz rodzajów urządzeń implantowanych podczas procedur. Ukierunkowanie, trwałość lub dynamika zmian trendów są jednak widoczne dopiero w dłuższych okresach, co jednocześnie pozwala na szacowanie wartości prognostycznych.

Materiał i metody. Oceną retrospektywną objęto zabiegi CIED wykonane w ośrodku w latach 2002–2015. Analizę badanego materiału przeprowadzono z wykorzystaniem informacji zawartych w dokumentacji medycznej, w tym w księgach zabiegowych i protokołach wykonanej procedury, oraz zaczerpnięto z przeprowadzonych poszpitalnych badań kontrolnych. W opracowaniu uwzględniono coroczną analizę wyodrębnionych grup zabiegów, takich jak implantacje pierwszorazowe (*de novo*), wymiany urządzeń, modernizacje (*up-grade*).

Wyniki. W badanym okresie przeprowadzono łącznie 7921 zabiegów z zakresu CIED. Stosunek odsetków kobiet do mężczyzn wynosił 52% v. 48% (śr. wieku: 72,7 roku).

Implantacje *de novo* stanowiły 68,5% wszystkich wykonanych procedur, wymiany urządzeń z powodu wyczerpywania się baterii zasilających dotyczyły 24,4% przypadków, a 7,1% stanowiły pozostałe zabiegi. W grupie pierwszorazowych procedur wszczepienia stymulatorów (PM) dotyczyły 81,7% zabiegów, w tym: przedsionkowych (AAI) — 6,2%, komorowych (VVI) — 49,6%, przedsionkowo-komorowych (DDD) — 43,8%. Pozostałe 18,3% procedur *de novo* tworzyły w 83,2% układy kardiowertująco-defibrylujące (ICD), w tym w 26,0% — ICD-DR, w 57,2% — ICD-VR, a w 16,7% — wzbogacone o funkcję resynchronizacji CRT-D. Modernizacje w obrębie układów stymulujących objęły 82,4% wszystkich zabiegów o charakterze *up-grade*. Zabiegi *up-grade* wzbogacające dotychczasowy układ o urządzenie z nowymi funkcjami, takimi jak przerywanie tachyarytmii komorowych (do → ICD) i/lub resynchronizację serca (do → CRT-D), stanowiły 17,6% wszystkich modyfikacji.

Wnioski. Wzrostowi ogólnej liczby wykonywanych zabiegów CIED towarzyszyło zwiększanie udziału zakładanych urządzeń z rozszerzonym zakresem terapii o funkcje antyarytmiczne i/lub resynchronizujące zarówno w grupach zabiegów *de novo*, jak i *up-grade*. Szacowane wartości prognostyczne wskazują na utrzymanie się trendu wzrostu liczby wykonywania procedur CIED z urządzeniami analizowanych w opracowaniu.

Słowa kluczowe: wszczepialne kardiowertery-defibrylatory, stymulatory serca, badanie retrospektywne

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