The cost of CIED infectious complications treatment in Poland from the perspective of Polish hospitals

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ABSTRACT

Introduction: Cardiac implantable electronic devices (CIED) are a recognized form of therapy in cardiology. Apart from the benefits, the use of CIEDs is also associated with the risk of complications, and the most important ones influencing treatment results and prognosis are infectious complications.

Aim: This study aimed to calculate the cost of treatment of CIED-related infections, including transvenous lead extraction and device reimplantation, from the perspective of a Polish hospital.

Methods: A retrospective analysis of hospitalization costs of patients referred to transvenous lead extraction (TLE) for CIED infection was performed. The study covers cases from three Polish reference centers specializing in the comprehensive treatment of cardiac electrotherapy complications.

Results: It was shown that the average cost of treating a CIED infection is 34 000 PLN (8010 EUR) and is the highest in the cardiac resynchronization therapy with defibrillator function (CRT-D) group, where it amounts to almost 50 000 PLN (11 440 EUR). Thus, treatment of CIED infections is associated with an average loss of 3000 PLN for the healthcare provider and the length of hospitalization has a major influence on final outcomes.

Conclusions: The hospital cost of treatment of CIED-related infections was high and related mainly to the type of device and length of hospitalization. Despite the low utilization of costly extraction tools, the hospitalization was still likely to be unprofitable.

Key words: CIED-related infectious complications, healthcare costs, transvenous lead extraction

INTRODUCTION

Cardiac implantable electronic devices (CIEDs) have long been an important tool in the treatment of many cardiac diseases. Their use is associated with a significant improvement in the quality of life or better prognosis [1]. Continuous progress in this field and the development of electrotherapy have led to the implementation of more complex devices than standard pacemakers (PM), such as implantable cardioverter-defibrillators (ICD) and cardiac resynchronization therapy (CRT). Despite the benefits of CIEDs, there is a risk of complications. One of the most important problems is CIED-related infection, which leads to a number of consequences including an increased risk of death, the need for system removal and new implantation, or prolonged hospitalization [2].

Determining the prevalence of CIED infections is difficult due to the heterogeneity of the populations analyzed, the lack of a precise definition, and different methodologies used. There is a clear difference between the incidence of infection in prospective studies where a risk of 0.6%–1.3% [3, 4] is observed

WHAT'S NEW?

This was a multicenter Polish study that analyzed the contemporary real-world costs of treatment of cardiac implantable electronic device-related infections from the perspective of the healthcare provider and not the public payer. The results of the study analyses indicate a high cost of care despite low utilization of costly extraction tools, and that this cost may not be entirely covered by the dedicated National Health Fund tariffs.

compared to retrospective studies where the incidence of infection was 2.3%–3.4% [5, 6] within the first year of implantation. The most commonly isolated microorganisms are Staphylococcus aureus and coagulase-negative staphylococci [5]. Several risk factors for infectious complications have been identified such as renal failure, especially in the final stage with dialysis, history of device infections, diabetes, use of anticoagulants and antiplatelet agents, malnutrition, fever, and active infection before the procedure, temporary pacing, and long duration of the procedure [6, 7]. The cornerstone of CIED-related infection treatment is the extraction of the whole device together with leads (transvenous lead extraction [TLE]) and reimplantation of a new one after curing the infection. It seems that the best way to reduce the costs of treatment of infectious complications is their prevention [6, 8]. Preventive strategies with proven effectiveness include the creation of high-volume centers performing an appropriate number of procedures per center and operator, an appropriate surgical technique limiting the frequency of reinterventions, and the prevention of hemorrhagic complications [9]. In addition, the use of antibacterial envelopes, which reduce the risk of staphylococcal infections in high-risk patients, i.e. patients with *de novo* cardiac resynchronization therapy with defibrillator function (CRT-D) implantation and those undergoing device replacement procedures, has proved effective [10]. In scientific publications regarding cost analyses in cardiology in Poland, we can find single studies on the costs of outpatient treatment of patients with heart failure or the costs of treatment of patients with supraventricular arrhythmia [11, 12], and one single-center analysis of TLE costs, which showed an underestimation of the procedure's reimbursement TLE [13]. There is a general belief among Polish cardiologists that the reimbursement of these procedures based on diagnosis-related groups of patients (DRG) is underestimated and in most cases does not cover the costs of standard tools used during the procedure, thus discouraging the use of more modern and safer but more expensive techniques.

This study aimed to calculate the cost of treatment of CIED-related infections, including transvenous lead extraction and device reimplantation, from the perspective of a Polish hospital.

METHODS

A retrospective analysis of hospitalization costs of patients referred for TLE due to the CIED infection was performed. The study covers cases from three Polish reference centers specializing in comprehensive treatment of cardiac electrotherapy complications: Górnośląskie Centrum Medyczne im. prof. Leszka Gieca Śląskiego Uniwersytetu Medycznego w Katowicach, Szpital Kliniczny Przemienienia Pańskiego Uniwersytetu Medycznego im. Karola Marcinkowskiego w Poznaniu, and Kliniczny Szpital Wojewódzki Nr 2 im. Św. Jadwigi Królowej w Rzeszowie. As a case study, this analysis has no intent to mimic the whole population of patients with CIED infections. The analysis specifically covers patients hospitalized for CIED infections in the 2016–2018 period. Information on diagnostics, type of CIED, applied treatment and length of hospitalization was extracted from medical records. The extracted data were accompanied by information on the direct real gross costs of every good products and service contributing to patients' hospitalization outlays obtained from financial departments of individual centers. The financial data were then divided into the following cost categories: manhours (fixed cost of an hour of hospital stay), personnel, medical tests, total drugs and medical devices, antibiotics, CIED with leads, drugs and medical devices used either for extraction or implantation, as well as other drugs and medical devices. It needs to be borne in mind that, depending on how costs are calculated in a particular center, the category 'personnel' may not be consistent between analyzed centers, though the problem of inconsistency does not affect the total costs. Furthermore, the financial data on public payer reimbursement of each patients' therapy were also obtained, which made it possible to assess economic viability of CIED infection treatment in current systemic conditions.

In Poland, the treatment of CIED infections is reimbursed by the single central national insurer — the National Health Fund (NHF) based on the DRG — standard payment rates dependent on the diagnosis and treatment provided. This is the basic way of accounting for all hospitalizations in Poland. In exceptional cases, when the cost of hospitalization exceeds three times the valuation of the relevant DRG, the NHF may, but is not obliged, to cover the cost of hospitalization following a case-based decision. To maintain consistency and reproducibility of the results presented, hospitalizations financed in this way were excluded from the present analysis. Moreover, hospitalizations of patients who did not complete therapy in a given center and were subsequently transferred to other hospitals were excluded from the study, as in such cases the identification of the total cost of treatment was precluded. Our calculation does not take into account opportunity costs related to prolonged hospitalizations and

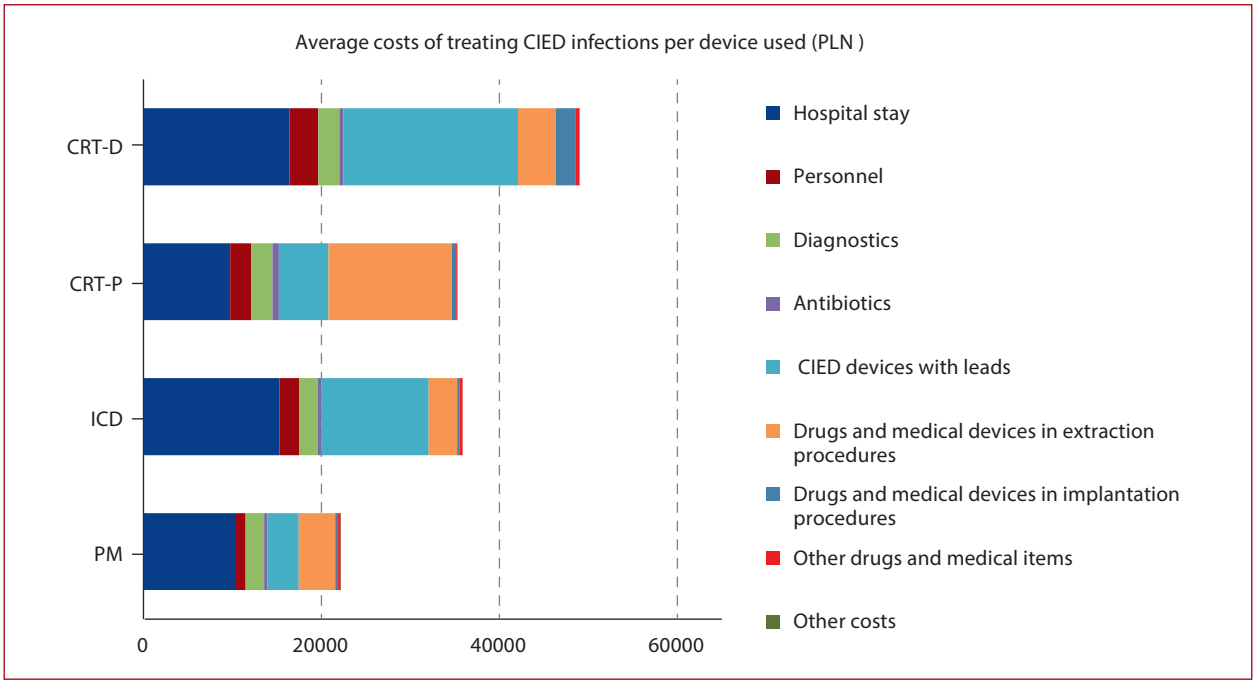

Figure 1. Average costs of treating CIED infections per device used (PLN)

Abbreviations: CIED, cardiac implantable electronic devices; CRT-D, cardiac resynchronization therapy with defibrillator; CRT-P, cardiac resynchronization therapy with pacemaker; ICD, implantable cardioverter-defibrillator; PM, pacemaker

additional costs of a cardiac surgery team being on alert in case of serious complications.

For each patient in the identified sample, the analysis included every cost element cataloged by a particular health center at their gross value in PLN. The costs were also presented in EUR, using the National Bank of Poland exchange rates from the end of each analyzed year (mean exchange rate 1 EUR = 4.3 PLN).

Statistical analysis

The cost elements were grouped in categories mentioned earlier while the results were presented using descriptive statistics for the analyzed sample in the form of the average cost of treating a patient with a CIED infection in the analyzed sample. Descriptive statistics were applied to investigate cost categories with the highest impact on the financial result of CIED infection treatment. Variables were summarized with mean (standard deviation [SD]) or as counts and percentages while the basic ones were also analyzed for their skewness using Pearson's formula. Additionally, median and quartile deviation was included for the variables that exhibit a relatively high skewness. The relatively high amount of data, which includes the type of CIED used, sex, age, types of extraction devices used, etc. allowed for further analysis in the form of statistical regressions, used specifically to identify factors influencing hospitals' financial results for each treatment. The statistical regression was used to analyze the relationship between the number of hospitalization days and the profit/loss per treatment. Standard significance level of 5% was applied, while the presented regression met the requirements of homoscedasticity, lack of residuals' autocorrelation, and normal distribution of the residuals. All calculations were performed using MS Office Excel and PSPP GNU.

RESULTS

Between 2016 and 2018, 169 patients with CIED infections were treated at three reference centers: 17 hospitalizations were billed individually and for a further 81 cases treatment data were incomplete (part of the treatment process was carried out at another center). The exclusion of these patients from the sample most probably results in the underestimation of treatment costs against the overall number of CIED infections treated in the chosen medical centers. Finally, data from 71 hospitalizations were included in the final analysis. In 80.3% of cases, pocket infection was diagnosed, whereas the remaining 19.7% of patients experienced systemic infection.

In the study group, the average cost of treatment of a CIED infection was 34 346 PLN; SD 17 342 (8010 EUR) and was the highest in the CRT-D group, where it reached 49 038 PLN; SD 11 583 (11 440 EUR) (Figure 1). Mean treatment cost in the case of pocket infection was 3206 PLN; SD 16 601, whereas in the case of systemic infection the cost amounted to 43 627 PLN; SD 17 794. There was no sign of total costs' distribution skewness.

Two categories of direct costs account for more than two-thirds of the total costs of treating CIED infections. These are hospital stay costs (39.1% of total costs) and CIED devices including leads (31.2% of total expenditure). The costs of the devices depend on the type of device

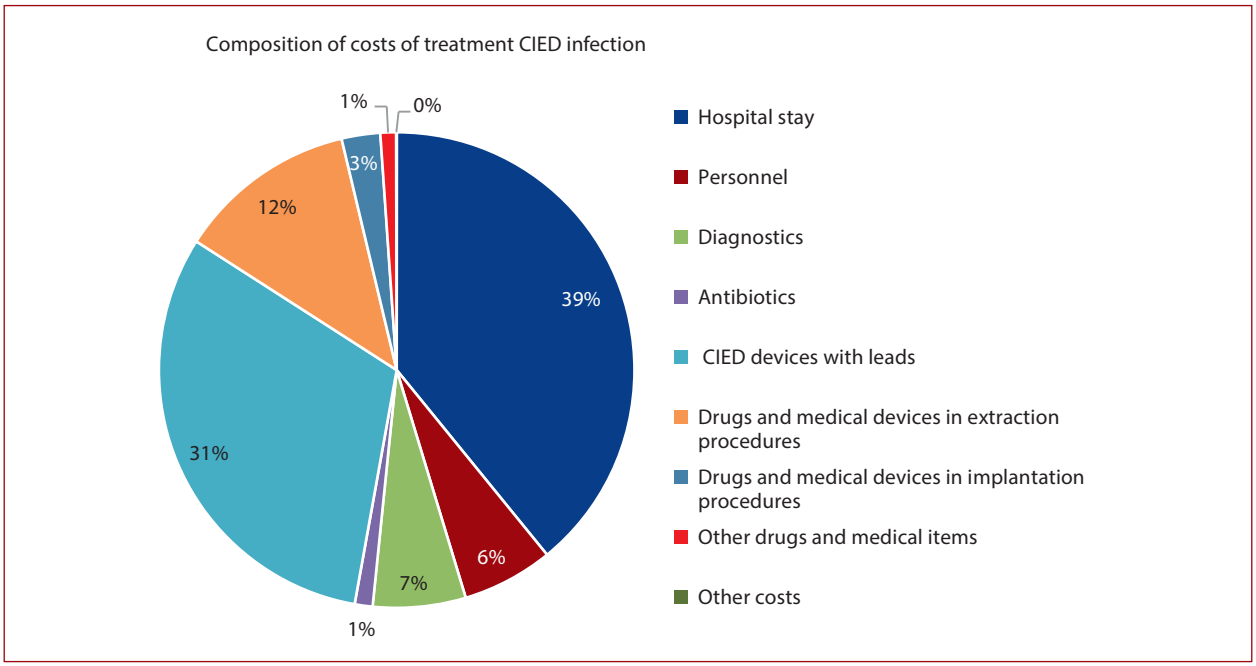

Figure 2. Composition of costs of treatment of CIED infections
Abbreviations: see Figure 1

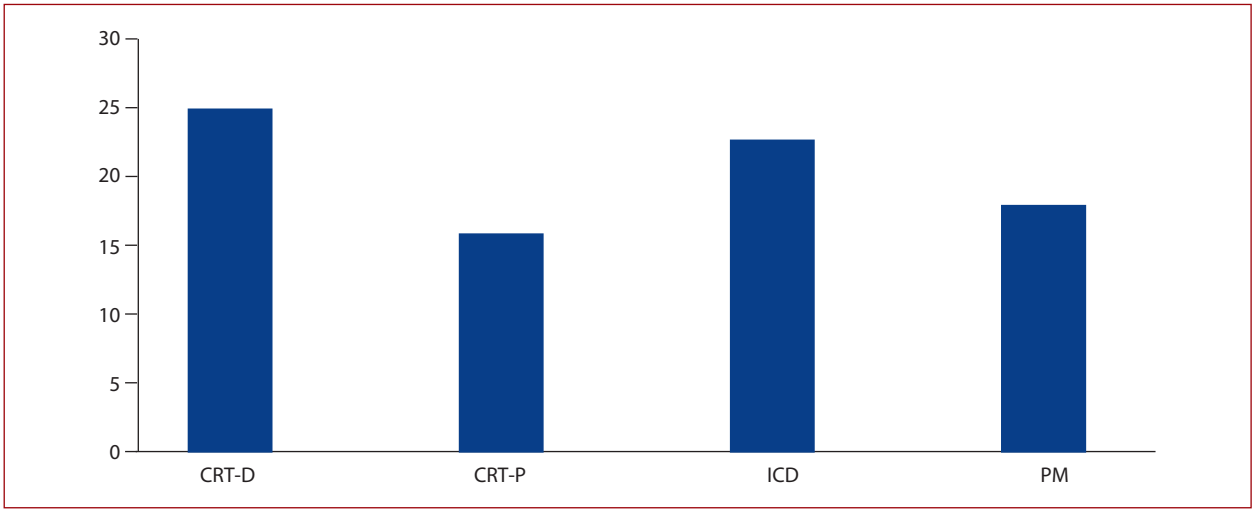

Figure 3. The average number of hospitalization days
Abbreviations: see Figure 1

used, with CRT-Ds being the most expensive devices on average (Figure 2).

The distribution of expenditures on patient treatment in the study group depended on the type of device. As only two patients underwent cardiac resynchronization therapy with peacemaker function (CRT-P) implantation, the interpretation of their treatment costs is highly dependent on case characteristics.

For PM and ICD systems, the largest cost category was hospital stay (Figure 2). Among patients with the relatively most complex CRT-D system, it was the device costs that had been highest when compared with other categories. Nevertheless, hospital stay costs were relatively high.

The cost of devices increased proportionally to their complexity while the cost of hospitalization depended on the length of hospital stay. The longest stays were for patients with the most complex systems and resulted from the need to treat infection before reimplantation. The average length of stay was 21 days: SD 11 for all patients.

Distribution of days spent in hospital in the study group (Figure 3).

The high cost of hospitalization resulted not only from the length of stay but also from the more frequent need

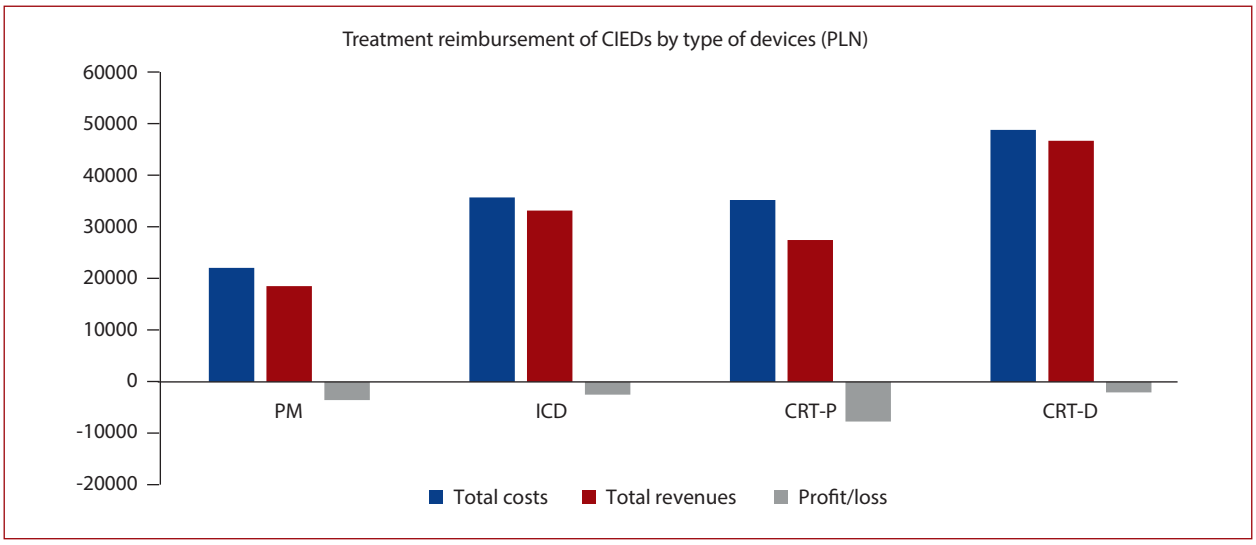

Figure 4. Treatment of reimbursement of cardiac implantable electronic devices (CIED) by type of devices
Abbreviations: see Figure 1

Table 1. Detailed breakdown of CIED infection treatment (PLN) costs

	PM	ICD	CRT-P	CRT-D	Average
Hospital stay	10 283.67	15 297.59	9764.72	16 400.15	13 435.43
Personnel	1194.96	2236.85	2354.54	3241.49	2125.90
Diagnostics	2068.88	2033.21	2373.28	2381.15	2165.17
Antibiotics	384.98	406.87	733.35	447.23	419.63
CIED devices with leads	3504.36	12 063.70	5 551.96	19 629.88	10 728.66
Drugs and medical devices in extraction procedures	4111.34	3205.96	13 863.16	4223.43	4191.24
Drugs and medical devices in implantation procedures	307.06	297.78	507.91	2 210.89	900.28
Other drugs and medical items	302.91	332.39	126.20	480.19	360.34
Other costs	22.91	—	—	23.80	16.73
Total costs	22 181.07	35 874.36	35 360.46	49 038.21	34 345.79
Total revenues	18 634.53	33 348.38	27 610.96	46 940.97	31 388.66
Profit/loss	–3546.54	–2525.98	–7749.50	–2097.25	–2957.13

Abbreviations: see Figure 1

for prolonged monitoring and longer stay in the intensive care unit. In most cases, it was not possible to discharge a patient before reimplantation.

Considering the aforementioned costs of hospitalization, the costs of devices used for reimplantation and other financial outlays, in many cases the treatment of CIED infection complications was a source of financial loss for the hospital. The average financial loss related to the treatment of CIED infections for all types of devices in the study sample amounted to 2957 PLN, while the median equaled 1090 PLN, with a quartile deviation of 6253 PLN. The profit and loss distribution exhibits negative skewness.

The highest cost burden on average was related to patients with an implanted CRT-P system, but the low number of cases does not allow for valid conclusions to be drawn on this basis. The distribution of revenues and costs per device is shown in Figure 4.

The regression analysis revealed that the number of days a patient spends in the hospital was a statistically significant factor influencing financial losses (PLN –871.86; 95% confidence interval [CI], –1091.48–[652.24]; *P*-value <1%). With each additional day of stay in the facility, the hospital's financial result decreases on average by more than 870 PLN — a number higher than the average cost of one-day hospitalization.

The third largest cost category is the equipment and drugs used in the TLE procedure. These costs constitute on average 12% of all expenditures and on average equaled 4191 PLN, while the median equaled 3183 PLN with a quartile deviation of 2332 PLN. However, extraction expenditures were curbed by the application of basic, low-cost solutions instead of more effective and expensive extraction methods, e.g. rotational sheaths were used only in 6% of cases. Table 1 shows a detailed cost breakdown.

DISCUSSION

The main outcomes of the study which calculated costs of CIED-related infection treatment from the hospital perspective are: (1) the average cost of treatment of a CIED-related infection was 34 000 PLN and was highest in CRT-D patients; (2) the cost of hospital stay and CIED-device, including leads, were two main factors driving the cost of hospital-

ization; (3) the average financial loss for the hospital due to treatment of CIED-related infection amounted to almost 3000 PLN; (4) the use of rotational extraction sheets in the study population was very low (6%).

The study is the first in Poland to analyze the real costs of treatment of CIED-related infections from the perspective of the healthcare provider and not the payer. The analysis shows that patients with the most complex devices, i.e. CTD-D, are hospitalized for the longest time, and also the cost of the reimplantation device in this group is the highest. Therefore, in this group, the treatment of infectious complications is the most costly, and, moreover, patients with the most complicated devices run the highest risk of infectious complications. Taking into account the total cost of CIED-related infection treatment in the analyzed period in Poland, it amounted to an average of 34 000 PLN, i.e. 8010 EUR.

Diagnosis and treatment of CIED-related infection is an expensive procedure usually involving many days of hospitalization and the need to remove the infected device. Procedures for transvenous removal of CIEDs require, especially in the case of multiple leads, the use of additional tools like rotational sheaths or excimer laser that uses external energy in the process of separating leads from the vessel wall. This entails additional costs as the procedure reimbursement does not take into account its complexity or the number of tools necessary to perform it. The cost of using a mechanical sheath alone exhausts the reimbursement for the whole procedure – transvenous lead removal. Nevertheless, it should be noted that such solutions increase the success rates of the procedure to over 95% while reducing its perioperative risk. In the study group, mechanical sheaths were used in only 6% of procedures, which was probably due to their price and concern for the economic calculation. Another problem associated with the procedure of lead extraction is the need to implant a new system on the contralateral side or epicardial lead placement. Solutions that broaden the spectrum of therapeutic options include using leadless pacemakers, in which the entire system is contained in a small capsule implanted directly into the lumen of the right ventricle, and using subcutaneous implantable cardioverter-defibrillators (S-ICDs) without intravascular access. Both in the case of subcutaneous cardioverter-defibrillators and leadless pacemakers, a reduction in the risk of infectious complications was observed [13–15], especially in the latter case. It must be stressed that a comprehensive strategy is needed to limit the incidence of infectious complications, starting with the provision of appropriate standards in the operating room, diagnostics and pre-implantation treatment of asymptomatic infections, preparation of the patient and the operating field (surgical field), appropriate personnel training, perioperative antibiotic prophylaxis and, finally, using absorbable mesh envelopes that locally release highly concentrated antibiotics: minocycline and rifampicin in high-risk populations. The cost-effectiveness of gentamycin-collagen sponge as part of a multicomponent prevention strategy has also been reported [16].

Analysis of all costs has shown that the treatment of CIED infection is associated with an average loss of 3000 PLN per case. An optimal solution would be to change the way of financing the treatment of CIED infections, bearing in mind the need for additional reimbursement in more complex cases. The cost estimation of a TLE procedure according to DRG does not differentiate the scale of difficulty of these procedures, does not include the cost of involving a cardiosurgical team, and finally, despite the constantly rising hospital operational costs, its amount is not subject to appropriate valorization. A previous study on the TLE procedures reimbursement in our country from 2012 also indicated the lack of proper valuation [13]. Studies on the treatment costs of CIED infections in other countries are largely based on the information from the public payer and show that the treatment of infectious complications doubles the cost of care for patients with CIED within a year [14]. In a prospective study in France, the average cost of treating a CIED infection was 23 000 EUR for *de novo* implantations and 21 000 EUR for reimplantations [4]. An interesting conclusion is provided by a study of the American population from 2016, which shows that an additional cost of treating such infections exceeded 45 000 USD over 12 months [18]. A disadvantage of these calculations is the fact that this estimation is from the payer's perspective and does not reflect the actual cost accrued by the center, while its advantage is a large database. Few data are available from studies on the cost of treating CIED infections from a provider's perspective. The results then relate to two different healthcare systems, small groups of patients, and different periods analyzed. For example, the cost of treating a pacemaker-related infection was estimated at 11 555 EUR according to an analysis performed in Germany in 2010 [19], while a study conducted in 2019 in Manchester revealed the cost of 8000 GBP in the case of pacemakers and 22 000 GBP for CRT-Ds [20]. In our country, we do not have a consistent database to determine the actual frequency of infectious complications in CIED patients and to estimate the cost of treatment. The paucity of such data does not allow us to conclude that the NHF reimbursement for therapies in this group of patients is realistic. In 2019, some progress was made in the availability of therapies for the treatment of infectious complications in patients with CIED. This concerns the NHF's reimbursement for S-ICD implantations. Both antimicrobial envelopes, which reduce the risk of pocket infection, especially in high-risk patients, and leadless pacemakers should become part of services financed by the NHF.

Limitations of the study

The study is conducted retrospectively and prone to typical biases of this methodology. The presented results of the study have some limitations such as a relatively small but homogenous group and the involvement of three

high-volume hospitals — the results may be different in less experienced centers. The standard of cost calculation for different cost categories may differ between individual centers, but the total cost of hospitalization is comparable.

CONCLUSIONS

The hospital cost of treatment of CIED-related infections was high and related mainly to the type of device and length of hospitalization. Despite the rare use of costly extraction tools, the hospitalization was still likely to be unprofitable.

Article information

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