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ARTYKUŁ ORYGINALNY / *ORIGINAL ARTICLE*

The impact of remote monitoring of implanted cardioverter-defibrillator (ICD) and cardiac resynchronisation therapy device (CRT-D) patients on healthcare costs in the Silesian population: three-year follow-up

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Abstract

Background: The population of patients with implanted cardioverter-defibrillators (ICD) and cardiac resynchronisation therapy devices (CRT-D) is constantly growing. The use of remote-monitoring (RM) techniques in this group can significantly improve clinical outcomes, but there are limited data about the impact of RM on healthcare costs from a payer's perspective.

Aim: The aim of the study was to assess the impact on costs for the healthcare system of RM in patients with ICD or CRT-D.

Methods: We examined a cohort of 842 patients with ICD or CRT-D. The group was divided into two groups based on RM (or no RM [NRM]), matched according to important clinical characteristics. The subjects were followed for a maximum of three years after implantation (mean follow-up 2.11 ± 0.83 years). The overall costs for the healthcare provider in the follow-up were defined as the primary endpoint. The secondary endpoint was the use of different types of medical contact events: hospitalisation and number of in-clinic and general practitioner visits (without the number of remote transmissions).

Results: In the three-year follow-up, the reduction in the costs of treatment for National Health Care in the RM group was 33.5% (median value, $p < 0.001$). In patients with implanted CRT-D, the reduction reached 42.7% ($p = 0.011$), and with ICD it was 31.3% ($p = 0.007$). We observed no significant reduction in the median hospitalisation costs in the three-year follow-up in the RM group (p = NS), despite a 25% drop in the mean value. The costs of outpatient visits were slightly higher in the RM group (p = NS). In the follow-up period, there was no reduction in the number of medical contact events (p = NS).

Conclusions: Remote monitoring in patients with implanted ICD or CRT-D devices reduces the cost for the national healthcare provider.

Key words: remote monitoring, healthcare costs, heart failure, cardioverter-defibrillator

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INTRODUCTION

Over the last few years, the population of patients with implanted cardiac devices, especially implanted cardioverter-defibrillators (ICD), has provided novel opportunities for remote monitoring (RM). The idea of implementing RM was to improve the safety of patients, generally by three methods: first, early detection of the onset or progression of ventricular and atrial tachyarrhythmias; second, the early recognition of suboptimal device function; and, third, the identification of patients with symptomatic worsening or noncompliance to

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drugs. The benefit of ICD use in mortality reduction has been proven [1–4]. Additionally, in a recent published study, the INfluence of home moniToring on mortality and morbidity in heart failure patients with IMpaired lEft ventricular function (IN-TIME), a further reduction in all-cause mortality as well as in the combined endpoint, all-cause death, overnight hospital admission for heart failure, change in New York Heart Association (NYHA) Functional Classification class, and change in patient global self-assessment has been shown in the population provided with the RM system [5]. In this trial, after one-year follow-up, 18.9% of 333 patients in the telemonitoring group and 27.2% of 331 in the control group ($p = 0.013$) had worsened composite clinical scores. This difference was mainly caused by the lower mortality in the telemonitoring group than in the control group (10 vs. 27 deaths). What should be stressed is that the reaction time after telemonitoring alert was very short (one day to patient contact, two days to follow-up). The authors concluded that automatic, daily, implant-based, multi-parameter telemonitoring can significantly improve clinical outcomes for patients with heart failure [5]. Also in the MONITOR-ICD study, it was shown that RM significantly reduces the time needed for a decision on a given episode, emergency or urgent visits, and follow-up burden [6].

According to the Heart Rhythm Society (HRS) consensus statement on remote interrogation and RM released in 2015, a strategy of RM and remote interrogation, combined with at least an annual in-person evaluation, is recommended with class IA over a calendar-based schedule. Additionally, all patients with cardiac implantable electronic devices should be offered RM as part of the standard follow-up management strategy. The in-person evaluation schedule should be maintained at least every 6–12 months [7].

Despite the clinical and financial benefits, the most important reported barrier to the implementation of RM for all cardiac implantable electronic devices (CIEDs) is the lack of reimbursement. In a study published by Mairesse et al. [8], the authors sought to assess the implementation and funding of RM of CIEDs, including conventional pacemakers, ICD, and CRT devices, in Europe. Based on data from 43 centres in 15 European countries, RM was implemented in 22% of pacemaker patients, 74% of ICD patients, and 69% of CRT patients. In 80% of centres participating in this study, the most important barrier to the implementation of RM for all CIEDs was the lack of reimbursement [8]. What should be mentioned is that, despite the increasing workload with RM for physicians and specialised nurses, in fact (also in Poland) there is no reimbursement for RM.

So far, there has been very little data published on whether RM contributes to a reduced healthcare burden in relation to costs for the healthcare insurance providers.

The aim of the study was to assess the impact on costs for the healthcare system of RM of patients with ICD or cardiac resynchronisation therapy device (CRT-D).

METHODS

We examined a cohort of 842 patients who had undergone, between 2006 and 2014, the first implantation or generator exchange of a single- or dual-chamber ICD or CRT-D for primary or secondary prophylaxis of sudden cardiac death, according to current guidelines. There was no age restriction. The study was designed as a population-based, matched cohort study. The group was divided into two groups (RM and no RM [NRM]) and matched according to important clinical characteristics (age, left ventricular ejection fraction [LVEF%], implanted ICD/CRT-D ratio, gender, diabetes, chronic renal disease with glomerular filtration rate < 60 mL/min/m^2, prior myocardial infarction, myocarditis or cardiac arrest, hypertension, congestive heart failure, transient ischaemic attack or stroke, left bundle branch block, NYHA III/IV prior to implantation, and rhythm disturbances such as atrial fibrillation or relevant ventricular arrhythmias).

At inclusion, demographic data were collected: cardiac medication and current symptoms were recorded as well as an indication for ICD or CRT-D, aetiology of cardiac disease, and comorbidities.

The follow-up data, including use and cost for national healthcare provider, were obtained from the National Health Fund (*Narodowy Fundusz Zdrowia*, NFZ, the Polish national healthcare insurance company). The diagnosis, procedures, and costs for the healthcare provider were identical to those reported to the NFZ for settlement from general practitioners (GPs), specialised clinics, and hospitals.

The subjects were followed for a maximum of three years after implantation. Mean follow-up was 2.11 ± 0.83 years. The RM was activated during the first control visit, according to local protocol after a mean time of two weeks (maximum one month). The health economic evaluation was focused on patient follow-up. The costs of implantation and the first in-clinic visits were considered to be equal in both groups and were not included in the analysis. Every patient had at least one in-clinic visit per year. The overall costs for NFZ in the follow-up have been defined as the primary endpoint and were compared between the RM and NRM groups. The secondary endpoint was the use of different types of medical contact events: hospitalisation, and number of in-clinic and GP visits (without the number of remote transmissions). Payer costs were based on diagnosis-related groups and public general hospital tariffs. All costs were expressed in Polish Zloty (PLN). The cost per patient was described by the mean, standard deviation (SD), median, minimum, maximum, and 95% confidence interval (CI).

Statistical analysis

To describe patient baseline characteristics, we used means with SDs for continuous variables and frequencies with percentages for categorical variables. We summarised expen-

Table 1. Baseline characteristics of the matched groups

	RM	NMR	p (between groups)
Age [years]	61.94 (53.25–70.75)	62.80 (56.04–69.51)	0.8047
Left ventricular ejection fraction [%]	25.00 (20.00–30.00)	25.00 (22.00–30.00)	0.3631
Left ventricular end-systolic volume [mL]	132.00 (101.00–180.00)	134.50 (101.00–184.50)	0.699
Left ventricular end-diastolic volume [mL]	181.00 (142.50–234.50)	186.50 (140.00–246.00)	0.6292
Implanted cardioverter-defibrillator	205 (71.4%)	200 (69.7%)	0.6470
Cardiac resynchronisation therapy device	82 (28.6%)	87 (30.3%)	0.6470
Secondary prevention	10%	10%	1.00
Gender — male	241 (84%)	241 (84%)	1.000
Diabetes	118 (41.1%)	115 (40.1%)	0.7987
Chronic renal disease with GFR < 60 mL/min/m^2	81 (28.2%)	81 (28.2%)	1.000
Prior myocardial infarction	155 (54%)	160 (55.7%)	0.6749
Hypertension	156 (54.4%)	161 (56.1%)	0.67
Previous TIA	7 (2.4%)	5 (1.7%)	0.5596
Stroke	24 (8.4%)	22 (7.7%)	0.7585
History of atrial fibrillation	71 (24.7%)	77 (26.8%)	0.5670
Left bundle branch block	44 (15.3%)	45 (15.7%)	0.9082
NYHA III class	109 (38%)	105 (36.6%)	0.7299
NYHA IV class	29 (10.1%)	27 (9.4%)	0.7785

GFR — glomerular filtration rate; NYHA — New York Heart Association; NMR — non-remote-monitoring; RM — remote-monitoring; TIA — transient ischaemic attack

ditures using both means with SDs and medians with interquartile ranges (IQR). When comparing expenditures between groups defined by the RM strategy, we tested for differences using the Mann-Whitney U test. Normal distribution of data was assessed by means of the Shapiro-Wilk test. All tests were interpreted as two-sided with a 5% level of significance. All statistical analyses were performed using SAS software (version 9.4 SAS Institute, Cary, North Carolina, USA).

RESULTS

In the final analysis, after matching, there were 287 patients in each group, with no statistically important differences between the groups regarding important clinical characteristics. The mean age was 62.80 (56.04–69.51) years in the RM group vs. 61.94 (53.25–70.75) years in the NRM group ($p = 0.8047$). The mean LVEF was 25% (25.00%; 20.00–30.00% RM vs. 22.00–30.00% NRM; $p = 0.3631$). A CRT-D was implanted into 48.5% of the patients. The baseline characteristic of the groups is summarised in Table 1. The numbers of patients who finished the first, second and third year of follow-up were, respectively: in the RM group: 287; 262; 142 patients; in the NRM group: 287; 249; 165 patients.

There was the following distribution of device producers in the groups: NRM group — Medtronic (Minneapolis, MN, USA): 52.5%, Biotronik (Berlin, Germany): 25%, St. Jude Medical (St. Paul, MN, USA): 20.5%, Boston Scientific: 2%; in RM group: Carelink (Medtronic) in 5.1%, Merlin (St. Jude Medical) in 72% and Home Monitoring (Biotronik) in 22.9% patient were used.

At the three-year follow-up, the average reduction in costs of treatment in the RM group was 33.5% for the median value (4893.23 [IQR 1053.65–13763.60] vs. 7588.18 [IQR 2163.66–24881.68]; $p < 0.001$) (Fig. 1). In patients with an implanted CRT-D, the median reduction of costs reached 42.7% (4520.35 [IQR 934.15–13763.60] vs. 7901.35 [IQR 2325.26–32450.40]; $p = 0.011$) and with an ICD 31.3% (5196.93 [IQR 1096.28–13745.48] vs. 7571.35 [IQR 2106.18–24463.00]; $p = 0.007$) (Fig. 2). We observed no significant reduction in the median hospitalisation costs in the three-year follow-up, but the mean value dropped by 32% (14732.58 ± 15604.50 vs. 21662.86 ± 25242.63), with slightly higher costs for the first year after implantation in the RM group (p = NS). Costs of outpatient visits were slightly higher in the RM group (p = NS; Fig. 3). In the follow-up period, there was no reduction in the number of defined medical contacts: hospitalisations, GP, and outpatient visits (p = NS; Fig. 4).

Unfortunately, we do not have at our disposal many credible data regarding the amount of the transmissions and the means of medical reaction from the period included in the analysis. Considering the facts of similar alarm settings in remote monitoring transmissions and identical organisation of work in the Monitoring Centre, we feel it is safe to relate

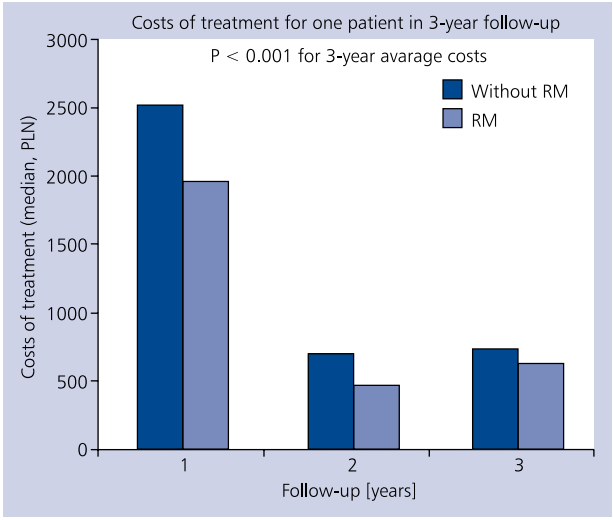

Figure 1. Comparison of treatment costs in patients with/ /without remote monitoring (RM)

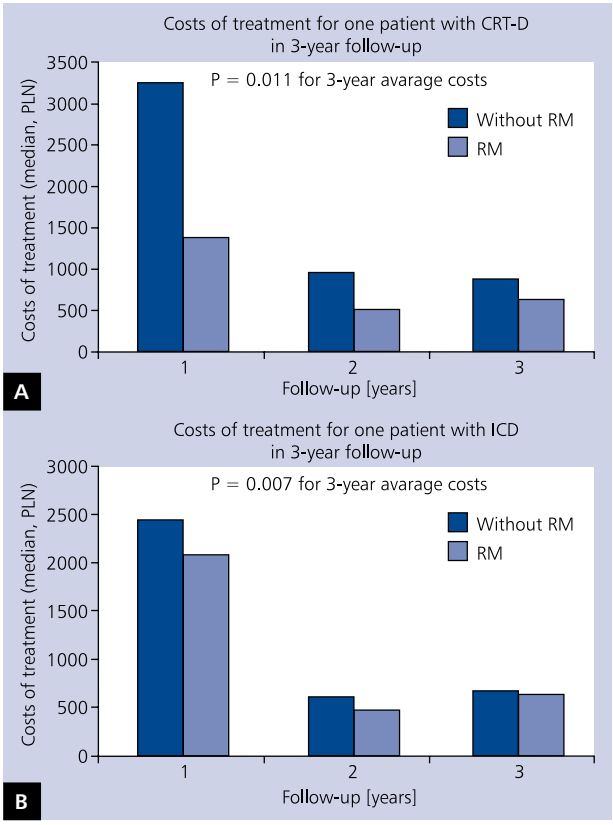

Figure 2. Comparison of treatment costs in patients with cardiac resynchronisation therapy devices (CRT-D) (**A**) or implanted cardioverter-defibrillators (ICD) (**B**), with and without remote monitoring (RM)

current results to the analysed population. Nowadays, we obtain an average of 856 remote transmissions per week, with 153 alerts and the need of patient additional in-clinic visit in seven patients.

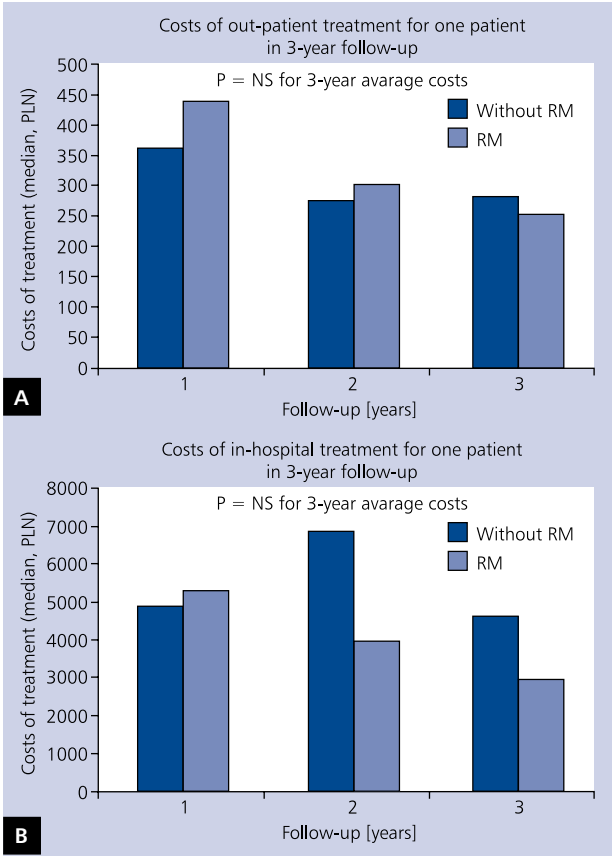

Figure 3. Comparison of out-patient (**A**) and in-hospital (**B**) treatment costs in patients with and without remote monitoring (RM)

A detailed summary of the costs is presented in Table 2, and costs distribution according to ICD10 classification in Figure 5.

DISCUSSION

In selected patients with heart failure and impaired left ventricular systolic function, treatment with ICD or CRT-D reduces all-cause mortality and the number of hospital admissions for heart failure and major cardiovascular events. An automatic telemonitoring report containing technical and rhythmic parameters has an additional beneficial effect in this group of patients [1–5]. As mentioned above, in the IN-TIME trial, the authors concluded that daily, implant-based, multi-parameter telemonitoring can significantly improve clinical outcomes for patients with heart failure [5].

The clinical benefit described above should theoretically be related to a cost reduction for healthcare systems. To the best of our knowledge, there have been only a few studies that have focused on this topic. An analysis of over 90,000 'real-world' patients recently presented by Piccini at the HRS 2015 Scientific Sessions showed that RM substantially lowers hospital payments. In this study, 34,259 patients with implanted devices were followed using both RM and scheduled

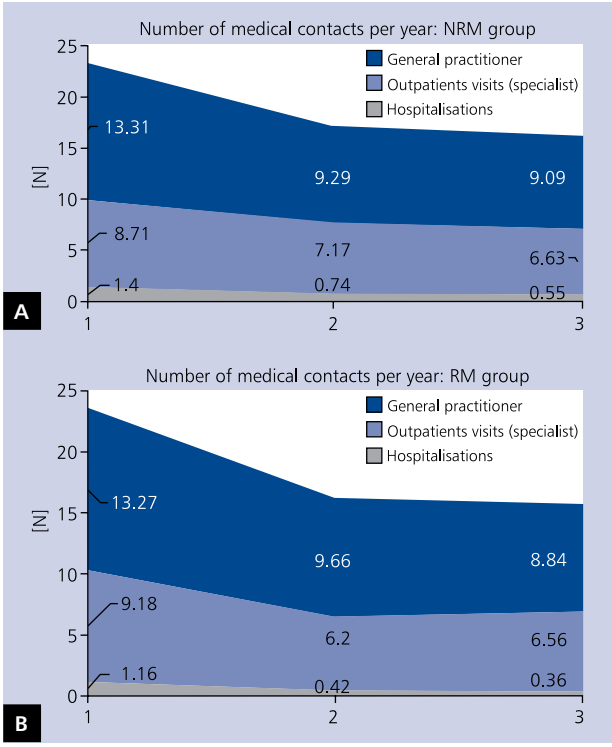

Figure 4. Number of different medical contacts in non-remote-monitoring (NRM) (**A**) and remote-monitoring (RM) (**B**) groups (without the number of remote transmissions); p = NS

clinic visits, compared with 58,307 with scheduled clinic visits only. The primary endpoint was all-cause hospitalisation that occurred later than one month after device implantation. The authors noted that, in the RM group, patients had significantly more heart failure and prior ventricular arrhythmias. The control group had more atrial fibrillation and prior cerebrovascular diseases. In our analysis, both arms of the study were matched for these clinical data to avoid any eventual impact on treatment cost and hospitalisation frequency. In Piccini et al.'s [9] analysis, the overall hospital costs for patients with RM dropped significantly ($p < 0.001$) compared with the control group with clinic visits only ($8,720 and $12,423 per patient-year, respectively). The biggest difference was shown in patients with defibrillating devices: costs dropped by 31% for pacemakers, 43% for ICD, 45% for CRT-D ($p < 0.001$ for all three), and 35% for CRT-P ($p = 0.117$). The authors suggest that for every 100,000 patient-years of follow-up, the use of RM is associated with about 9800 fewer hospitalisations, a 119,000-day drop in hospitalisation, and a $370,270,000 reduction in hospital payments, compared with a strategy of regular clinic visits [9].

In the prospective, multicentre trial, EuroEco (European Health Economic Trial on Home Monitoring in ICD Patients), the primary endpoint was the total follow-up-related cost for providers, comparing RM-facilitated follow-up (RM ON) with regular in-office follow-up (RM OFF) during the first two

Table 2. Detailed summary of costs at three-year follow-up

Year of follow-up	Mean	First quartile	Median	Third quartile	Mean	First quartile	Median	Third quartile	p
	NRM				RM				
Overall costs									
1	8925.74	451.80	2521.15	8056.70	5376.42	409.13	1959.80	6909.00	0.11
2	6419.77	188.60	702.40	5209.90	3242.78	184.00	478.78	2877.10	0.10
3	7050.63	211.60	740.15	4763.20	4126.49	205.60	636.80	3244.70	0.29
Patients with CRT-D									
1	11751.92	471.60	3269.60	10439.70	4927.34	337.35	1395.83	6278.15	0.03
2	5923.13	156.40	973.15	5818.40	3522.46	215.15	524.00	2732.00	0.45
3	5503.67	322.00	896.00	5831.00	3221.34	161.00	640.15	3813.30	0.2
Patients with ICD									
1	7696.35	424.55	2445.30	7359.18	5556.06	2081.80	2081.80	6909.00	0.6
2	6617.86	193.20	613.60	5209.90	3126.37	474.25	474.25	2877.10	0.12
3	7562.12	210.80	670.43	4359.00	4588.69	636.80	636.80	2912.40	0.62
Out-patient treatment									
1	674.56	190.50	364.48	664.28	645.70	245.40	441.05	744.05	0.01
2	624.18	119.60	276.00	543.45	512.14	138.00	302.30	514.90	0.36
3	920.83	142.60	283.10	584.15	457.78	146.60	254.98	547.80	0.80
In-hospital treatment									
1	13087.08	2415.00	4888.00	13760.00	9112.20	2703.00	5304.00	12740.00	0.96
2	13459.81	2444.00	6864.00	19249.76	8453.97	2439.30	3952.00	8162.00	0.03
3	11833.83	2496.00	4628.00	19711.00	10003.58	2444.00	2964.00	6864.00	0.24

CRT-D — cardiac resynchronisation therapy device; ICD — implanted cardioverter-defibrillator; NMR — non-remote-monitoring; RM — remote-monitoring

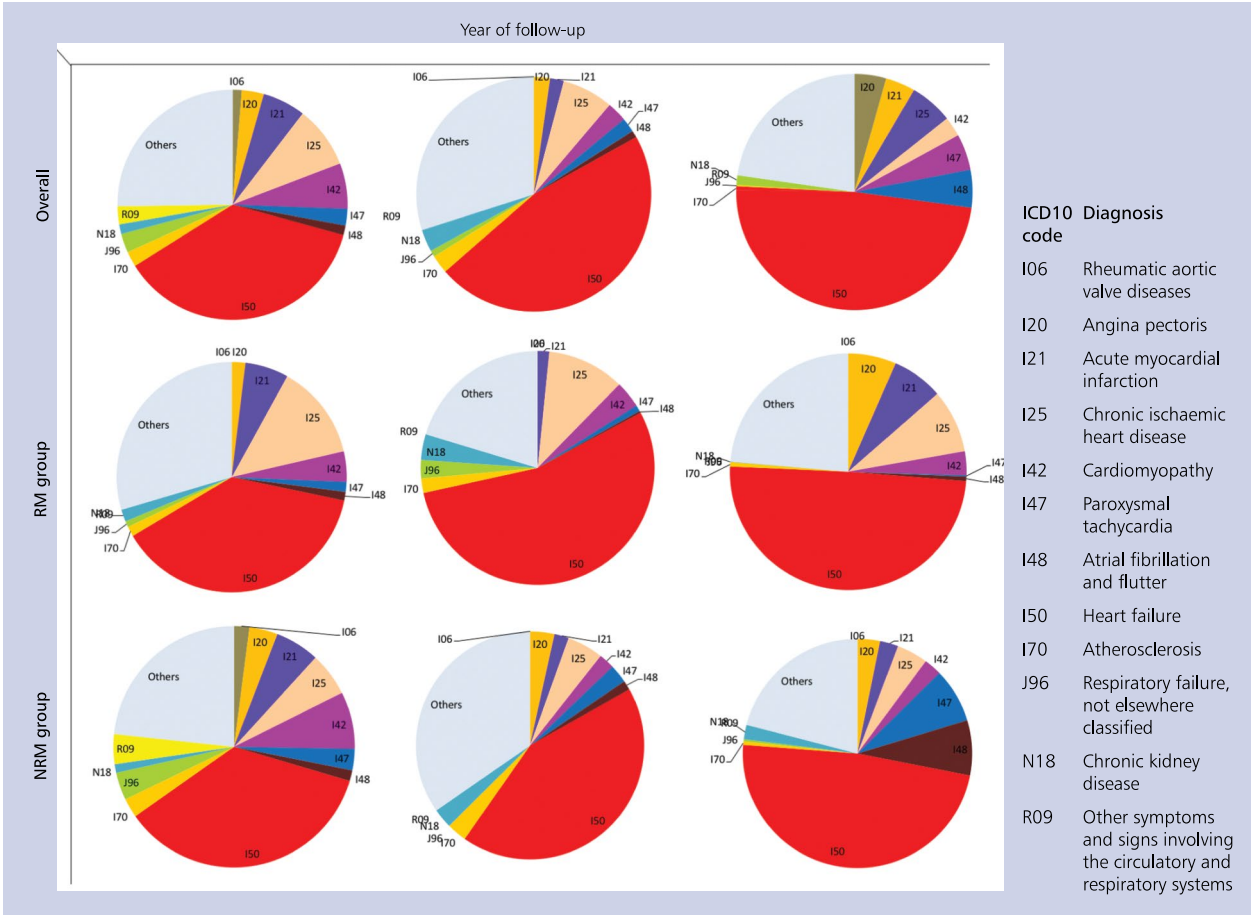

Figure 5. Cost distribution according to ICD10 classification (diagnosis reported for reimbursement) at three-year follow-up

years after ICD implantation. The final analysis was based on 303 patients with single-chamber (VVI) or dual-chamber (DDD) — ICD implants from 17 centres in six European Union countries (Belgium, Finland, Germany, the United Kingdom, Spain, the Netherlands), randomised to RM ON or OFF (159 vs. 144 patients, respectively). At baseline, in the RM ON group, the rate of patients with a primary prophylactic indication for ICD was higher. In the RM ON group there were fewer follow-up visits, despite a small increase in unscheduled visits, more non-office-based contacts, Internet sessions, and in-clinic discussions. Similarly to other previous reports, fewer hospitalisations (0.67 ± 1.18 vs. 0.85 ± 1.43, $p = 0.23$) and shorter length of stay were noted, although they were not significant. Finally, for the whole study population, the total follow-up cost for providers was no different for RM ON vs. OFF (mean [95% CI]: 204 [169–238] vs. 213 [182–243] Euro) [10]. The total decrease in costs from a payer's perspective over a two-year period was too small to be considered statistically significant. The main cost driver was the number of hospitalisation days for patients. In our analysis, there was no difference regarding the secondary endpoint — the numbers of outpatient and GP visits were comparable, and the decrease in hospitalisations was also not statistically important.

In the EuroEco trial there was no difference in the net financial impact on providers (profit of 408 Euro [327–489] vs. 400 Euro [345–455]; range for difference [2104 to 88 Euro], NS), but there was heterogeneity among countries. Less profit was noted for providers in the absence of specific remote follow-up reimbursement (Belgium, Spain, and the Netherlands) and maintained or increased profit in cases where such reimbursement exists (Germany and the United Kingdom) [10]. In our study, despite no reimbursement for RM, a significant reduction in costs was shown. As depicted in the figures, the costs remained lower in the RM group for every follow-up year. This financial impact in follow-up could be considered in the future as an important argument in the discussion about the expediency of RM reimbursement.

In the subanalysis, a different distribution of costs, according to diagnosis based on the ICD10 classification used for the report, was shown. Especially in the second year of follow-up, heart failure (ICD10: I50) was reported relatively more often,

responsible for most of the costs in the RM group. The next most common causes of hospitalisations were, respectively: chronic ischaemic heart disease (I25), cardiomyopathy (I42), respiratory failure (J96), and chronic kidney disease (N18). What should be stressed is that the absolute values of the costs were reported as higher in the NRM group for almost all diagnoses.

To summarise, in our study, a significant reduction in costs for the healthcare payer was shown. Compared with the mentioned EuroEco study, our group included both ICD and CRT-D patients, and was matched for clinical characteristics to avoid eventual bias in the results. On the other hand, the population was settled by one payer (NFZ) and was thus homogeneous for analysis.

Limitations of the study

Our study had some limitations, primarily the lack of information about the all-costs of healthcare, because private consultations are not reported to the NFZ, and the real cost of drug reimbursement. Secondly, it is difficult to assess the real costs for GPs because they are paid a flat rate 'per capita per year'.

CONCLUSIONS

Remote monitoring for patients with implanted ICD or CRT-D devices reduces the costs of healthcare.

Conflict of interest: *none declared*

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Wpływ zdalnego monitorowania pacjentów z implantowanym kardiowerterem-defibrylatorem (ICD) i kardiowerterem-defibrylatorem z opcją resynchronizacji (CRT-D) na koszty leczenia dla systemu opieki zdrowotnej w populacji Śląska: obserwacja 3-letnia

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Streszczenie

Wstęp: Populacja chorych z implantowanym kardiowerterem-defibrylatorem (ICD) i urządzeniami z opcją terapii resynchronizującej (CRT-D) stale rośnie. Zastosowanie technik zdalnego monitorowania (RM) w tej grupie osób może korzystnie wpłynąć na odległe wyniki leczenia, jednak brakuje danych na temat wpływu RM na koszty leczenia z punktu widzenia płatnika.

Cel: Celem badania była ocena wpływu zdalnego monitorowania pacjentów z ICD i CRT-D na koszty terapii dla systemu opieki zdrowotnej w rzeczywistej populacji chorych.

Metody: Do badania włączono populację 842 chorych z ICD lub CRT-D, podzieloną wg zastosowania zdalnego monitorowania (grupa z RM oraz bez RM [NRM]) na dwie grupy dopasowane pod względem istotnych parametrów klinicznych. Okres obserwacji wynosił maksymalnie 3 lata od implantacji (średni czas obserwacji: 2,11 ± 0.83 roku). Pierwotny punkt końcowy zdefiniowano jak łączny koszt opieki dla płatnika świadczeń, a drugorzędowy punkt końcowy — jako liczbę różnych form kontaktu ze służbą zdrowia: hospitalizacji oraz wizyt w poradni kardiologicznej i lekarza podstawowej opieki zdrowotnej.

Wyniki: W trakcie 3-letniej obserwacji redukcja kosztów leczenia dla Narodowego Funduszu Zdrowia w grupie RM wyniosła 33,5% (mediana; $p < 0,001$). Wśród pacjentów z CRT-D redukcja kosztów wyniosła 42,7% (mediana; $p = 0,011$), a w grupie z ICD — 31,3% (mediana; $p = 0,007$). Nie stwierdzono istotnej statystycznie różnicy w zakresie mediany kosztów hospitalizacji w grupie RM, mimo 25-procentowej redukcji dla wartości średniej. Koszty wizyt ambulatoryjnych były nieistotnie statystycznie wyższe w grupie RM ($p = NS$). Nie zanotowano znamiennego obniżenia liczby kontaktów ze służbą zdrowia w obserwacji odległej ($p = NS$).

Wnioski: Zastosowanie zdalnego monitorowania u pacjentów z implantowanym ICD lub CRT-D redukuje koszty leczenia dla systemu opieki zdrowotnej.

Słowa kluczowe: zdalne monitorowanie, koszty leczenia, niewydolność serca, kardiowerter-defibrylator

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