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COMPARATIVE ASSESSMENT OF CARDIAC ARRHYTHMIAS AND CLINICAL AND ECONOMIC ANALYSIS USING REMOTE TELEMETRY IN ELDERLY AND SENILE PATIENTS FOLLOWING DUAL-CHAMBER PACEMAKER IMPLANTATION

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Aim. To compare the frequency and timing of cardiac arrhythmia detection and conduct a clinical and economic analysis of remote telemetry (RT) in elderly and senile patients following dual-chamber pacemaker (PM) implantation compared to in-person clinical follow-up over a 12-month period.

Methods. A prospective study was conducted involving 92 patients (50% female), with a mean age of 71,5 years. The intervention group (n=39) was monitored remotely using the Medtronic CareLink Network, USA, with patients transmitting data monthly for one year. The control group (n=53) underwent in-person clinical follow-ups at one month and one year post-implantation. The groups were comparable in age, sex, clinical diagnoses, and complications (p>0,05). A cost-effectiveness analysis (CEA) was performed, and the cost-effectiveness ratio (CER) was calculated.

Results. No statistically significant differences were observed between the experimental and control groups in the frequency of cardiac arrhythmias. However, significant differences were found in the timing of arrhythmia detection (p<0,001), with earlier detection in the experimental group. According to the results of the clinical and economic cost-effectiveness analysis, the CER value for the remote monitoring method (33226,30 [33226,30; 33226,30]) is statistically significantly lower than the similar coefficient for in-person diagnostics (373542,00 [3735,42; 373542,00]).

Conclusion. The use of RT in elderly and senile patients following dual-chamber PM implantation did not show a statistical difference in arrhythmia detection rates. However, cardiac arrhythmias were diagnosed earlier in the experimental group. The cost-effectiveness analysis demonstrated that RT requires lower financial costs to achieve a unit of effectiveness compared to in-person monitoring.

Key words: clinical and economic analysis; pacemaker; remote telemetry.

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There is a steady global increase in the number of patients with cardiovascular implantable electronic devices (CIEDs), such as pacemakers (PMs), implantable cardioverter-defibrillators (ICDs), and cardiac resynchronisation therapy (CRT) devices. In Russia, in 2022, antiarrhythmic devices were implanted in 53,486 patients across 211 medical institutions (compared to 50,646 in 2021), with an overall growth of 36.4% in CIED implantations from 2013 to 2022 [1]. The implantable systems themselves are becoming more sophisticated, requiring more time for evaluation due to the presence of a complex microcomputer that assesses both the device's function and the detection of rhythm disturbances in patients.

Following the implantation of dual-chamber P in adult patients, it is recommended to conduct two follow-up tests within six months and then at least once annually [2].

In recent decades, telemedicine has increasingly been used for monitoring patients with CIEDs. The COVID-19 pandemic accelerated this trend, prompting both patients and healthcare professionals to adopt new means of communication [3]. The review of data obtained through remote telemetry (RT) allows for the evaluation of virtually all detected arrhythmias, comparable to in-clinic follow-up assessments of PM function. RT enables the quantification of ventricular and supraventricular ectopic beats, while intracardiac electrograms (IEGMs) provide differential diagnosis between supraventricular tachycardia (SVT) and ventricular tachycardia (VT), as well as the detection of atrial fibrillation (AF) or atrial flutter (AFL). V. Russo et al. (2022) demonstrated that RT leads to a shorter interval between the occurrence of atrial high rate episodes (AHREs) and clinical evaluation by a physician compared to in-clinic monitoring [4].

The ASSERT study (2017) established that prolonged AHREs are significantly associated with an increased risk of acute cerebrovascular events (stroke) or

systemic embolism [5]. In such patients, anticoagulant therapy reduces the risk of thromboembolic complications compared to aspirin, albeit with an increased risk of serious bleeding [6].

RT also offers advantages in the detection and assessment of clinical events [4, 7, 8] compared to conventional clinic visits. The TRUST study demonstrated a nearly 50% reduction in clinic workload (mainly due to the elimination of routine, non-contributory device checks) without compromising patient safety, as well as a reduction in the average time to evaluate clinically significant events to 3 days [9].

There are also studies demonstrating the economic efficiency of RT compared to in-person follow-up [10, 11]. For instance, the PONIENTE study revealed significant healthcare cost savings (for both patients and institutions) [12]. However, according to researchers, over five years of follow-up, RT in elderly patients with pacemakers may prove to be a more expensive alternative to clinic-based monitoring.

The Norwegian NORDLAND study, published in 2022, indicated that total costs per patient monitored via RT were higher, though the difference was not statistically significant [13]. No comparable studies conducted in Russia were found in the available literature. Nevertheless, despite the advantages of remote PM monitoring, in real-world Russian clinical practice, in-person visits to healthcare institutions remain predominant for the assessment of pacemaker function.

Study aim: To compare the frequency and timing of arrhythmia detection and to conduct a clinical and economic analysis of remote telemetry in elderly and senile patients after dual-chamber pacemaker implantation, in comparison with conventional in-clinic follow-up over a 12-month period.

METHODS

The present study is a prospective, single-centre investigation that included 92 patients (aged 60 to 88 years) following initial dual-chamber PM implantation at the Department of Surgical Treatment of Complex Cardiac Arrhythmias and Cardiac Pacing. The indications for pacemaker implantation were second- or third-degree atrioventricular block and sick sinus syndrome with clinical manifestations.

Inclusion criteria were as follows: age 60 years or older; no documented history of tachyarrhythmias; no ongoing antiarrhythmic therapy; indication for dual-chamber PM implantation; the patient's (or caregiver's) ability to understand instructions for remote data transmission and willingness to comply with them.

Exclusion criteria included: presence of a PM model incapable of recording and storing intracardiac electrograms (IEGM); severe or decompensated somatic comorbidities; thyroid dysfunction; documented episodes of tachyarrhythmias; and ongoing antiarrhythmic therapy.

Withdrawal criteria were: patient refusal to continue participation in the study and the presence of marked cognitive impairment.

Table 1.

Clinical and demographic characteristics of the patients included in the study

Parameter	Test Group (n=39)	Control Group (n=53)	p-value
Age, years	71.1±6.9	71.8±8.4	0.406
Male sex, n (%)	18 (46.2)	28 (52.8)	0.406
Female sex, n (%)	21 (53.8)	25 (47.2)	
Body mass index, kg/m^2	28.2 (25.7-30.9)	27.2 (24.2-30.1)	0.207
Body surface area, m^2	1.9 (1.82-2.04)	1.9 (1.86-1.97)	0.857
Indications for pacemaker implantation, n (%)			
Atrioventricular block	23 (59.0)	37 (69.8)	0.292
Sick sinus syndrome	16 (41.0)	16 (30.2)	
Comorbidities, n (%)			
Cardiac arrhythmia	38 (97.4)	52 (98.1)	1
Stable angina pectoris	4 (10.3)	10 (18.9)	0.251
History of myocardial infarction	6 (15.4)	10 (18.9)	0.654
Hypertension	39 (100)	51(96.2)	0.259
CHF	39 (100)	53 (100)	
Class I	2 (5.1)	9 (17)	0.202
Class II	14 (35.9)	20 (37.7)	
Class III	23 (59)	25 (47.1)	
Class IV	0 (0)	0 (0)	
CVA	3 (7.7)	2 (3.7)	0.648
Diabetes mellitus	11 (28.2)	9 (17)	0.204

Note: CHF - Chronic Heart Failure; CVA - cerebrovascular accident

The study was conducted in accordance with the principles of the Declaration of Helsinki and was approved by the local ethics committee (Protocol No. 9 dated 11 March 2024). All patients provided written informed consent for participation in the study and for the surgical intervention.

All patients received dual-chamber PMs equipped with IEGM recording capabilities. After enrolment, patients were divided into two groups. The intervention group (n = 39) was provided with a MyCareLink patient monitor (Model 24950, USA) to enable remote data transmission. These patients submitted data monthly via the Medtronic CareLink server for one year following implantation. The control group (n = 53) was monitored in the clinic one month and then one year after surgery. The intervention and control groups were comparable in terms of age, sex, nosological categories, and clinical-demographic characteristics. The results are presented in Table 1.

Statistical Analysis

Statistical processing of the data and graphical presentation of the results were performed using Statistica 13.0 (StatSoft Inc., USA, licence No. AX003J-115213FAACD-X), SPSS Statistics 20 (IBM SPSS, USA), GraphPad Prism 9.0 (GraphPad Software, USA), and Microsoft Office XP (Microsoft, USA). For quantitative data, the distribution pattern was assessed using the Shapiro-Wilk test, while homogeneity of variances was evaluated using Levene's test.

Variables with a distribution deviating from normal (nonparametric data) were analysed using the Kruskal-Wallis test. Dunn's test was used for multiple comparisons, and the Mann-Whitney U test was employed to compare nonparametric quantitative variables between two independent groups. For qualitative dichotomous variables, comparisons between independent groups were performed using the two-sided Fisher's exact test.

Differences were considered statistically significant at $p < 0.05$. For quantitative variables with a non-normal distribution, the median (Median) and interquartile range (lower quartile; upper quartile) were calculated. For qualitative dichotomous variables, frequencies (%) were reported [14].

Cost-effectiveness clinical and economic analysis

For the purposes of this study, a cost-effectiveness analysis (CEA) was performed, along with the calculation of the cost-effectiveness ratio (CER), to assess whether the costs of remote versus in-clinic monitoring over a 12-month period were justified by their clinical effectiveness, and to determine the more economically favourable approach, defined as the one with the lower CER value.

The CER (reflecting the cost per unit of effectiveness) was calculated using the following formula:

$CER = DC / Ef,$

where DC represents direct costs, and Ef denotes the monitoring effectiveness.

The lower the CER value, the lower the cost per unit of effectiveness, thus indicating a more economically advantageous method of patient follow-up [15].

For the purpose of this analysis, the primary criterion for clinical effectiveness was the timely detection of rhythm disturbances (AHREs, AF, atrial flutter, supraventricular tachycardia, or ventricular tachycardia) in both the remote monitoring and control groups.

Detection of the rhythm disorder within the same calendar month in which it occurred was considered to reflect 100% detection effectiveness (1.0). If the event was detected after the month in which it occurred, effectiveness was reduced to 1% (0.01) for the purpose of analysis, as the use of zero values was not permitted within the model.

The CEA included only those patients in both the remote and control groups who experienced a detected arrhythmia over the 12-month observation period. In cases where a single patient experienced multiple rhythm disturbances, each event was evaluated separately. For the CEA calculations, the sample included all such events: n = 53 for the control group and n = 39 for the remote monitoring group. When converting days to months for analytical purposes, a uniform 30-day month was assumed.

Sources of Cost Data for Detection

The cost of the equipment used for remote patient monitoring was obtained from Medtronic and amounted to 30,000 RUB per patient. According to standard practice in the Ryazan region, in-person follow-up involves a patient visiting a general practitioner (GP) for an electrocardiogram (ECG) and referral to a cardiologist at the Ryazan Regional Cardiology Dispensary, where the device follow-up is conducted. Notably, this follow-up service is not reimbursed under the regional compulsory health insurance fund (TFOMS). All visits to medical facilities are free of charge for patients.

According to TFOMS reimbursement rates: one GP consultation is valued at 744.20 RUB; one cardiologist consultation at 954.42 RUB; fn ECG at 169.09 RUB. Thus, the total cost of an in-person monitoring episode reimbursed by TFOMS amounts to 3,735.42 RUB.

According to our institutional data, the time required to review a single remote transmission (including completion of electronic medical records and patient communication) averages 30 minutes. Under the remote monitoring (RM) protocol used in this study, 11 transmissions were conducted per patient (one per month), with the estimated cost per transmission at 293.30 RUB (data from the Regional Clinical Cardiology Dispensary, Ryazan). Therefore, the total remote monitoring cost per patient amounted to 3,326.30 RUB.

Table 2.

Detected arrhythmias

	Control Group (n=53)	Test Group (n=39)	p-value
AHRE, n (%)	25 (47,2)	15 (38,5)	0,438
AF, n (%)	10 (18,9)	3 (7,7)	0,226
AFL, n (%)	3 (5,7)	0	0,261
SVT, n (%)	8 (15,1)	11 (28,2)	0,130
VT, n (%)	11 (20,7)	11 (28,2)	0,463

Note: AHRE - atrial high rate episodes; AF - atrial fibrillation; AFL - atrial flutter; SVT - supraventricular tachycardia; VT - ventricular tachycardia.

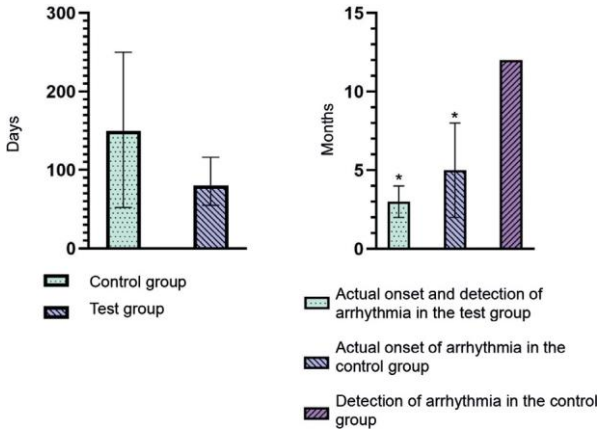

Figure 1. Left: Actual onset of arrhythmia episodes (Median [Q1; Q3] in days, p = 0.077). Right: Comparison of actual onset and detection time of arrhythmias in the intervention and control groups (Median [Q1; Q3] in months, *p < 0.05 compared to detection time in the control group). See text for details.

Sensitivity Analysis of the Cost-Effectiveness Analysis

To evaluate the robustness of the cost-effectiveness analysis results, a deterministic one-way sensitivity analysis was performed. This assessed the impact of varying the cost estimates for both remote and in-clinic monitoring by ±10%, simulating plausible real-world fluctuations in healthcare expenditure. The analysis revealed how such changes in cost assumptions would affect the cost-effectiveness ratio (CER) values and, consequently, the comparative economic preference for either monitoring strategy [16].

RESULTS

In both the intervention and control groups, no statistically significant differences were observed in the incidence of rhythm disturbances, including AHREs ($p = 0.438$), AF ($p = 0.226$), atrial flutter (AFL) ($p = 0.261$), SVT ($p = 0.130$), and VT ($p = 0.463$) (Table 2).

Similarly, there were no significant differences between the groups regarding the actual time to onset of rhythm disturbances measured in days from the beginning of the study ($p = 0.077$) (Fig. 1). However, in the control group, there was a statistically significant delay ($p < 0.001$) between the actual month of rhythm disturbance onset and the month of its detection, with detection occurring considerably later than the event itself.

In contrast, in the remote monitoring group, arrhythmias were detected in the same month as their actual occurrence, resulting in a significantly shorter detection latency compared to the control group ($p < 0.001$) (Fig. 2). Consequently, the groups differed significantly in terms of detection efficiency ($p < 0.001$) (Table 3).

The CEA demonstrated that the CER for remote monitoring was statistically significantly lower than that for conventional in-clinic monitoring ($p < 0.001$) (Fig. 3). This indicates a higher economic value for remote monitoring in terms of cost per timely detection. The findings were further confirmed by deterministic one-way sensitivity analysis, which also showed a statistically lower CER for remote monitoring ($p < 0.001$), demonstrating the robustness of the results.

Each patient in the intervention group underwent 11 scheduled remote transmissions. However, considering that the majority of rhythm disturbances (AHRE, AF, AFL, SVT, VT) in the remote group occurred during months 2, 3, and 4, an alternative transmission schedule was evaluated for potential optimisation. This hypothetical schedule included transmissions in months 1, 2, 3, 4, 6, 8, 10, and 12.

Under this modified scheme, although a slight decrease in diagnostic efficiency was observed (based on the original clinical effectiveness metric), the intervention group remained significantly more effective than the control group in detecting arrhythmias in a timely manner ($p < 0.001$) (Table 3).

Furthermore, even with the reduced number of transmissions, the CER for remote monitoring remained significantly lower than that of in-clinic follow-up ($p = 0.041$) (Fig. 4). These findings were likewise confirmed by the sensitivity analysis.

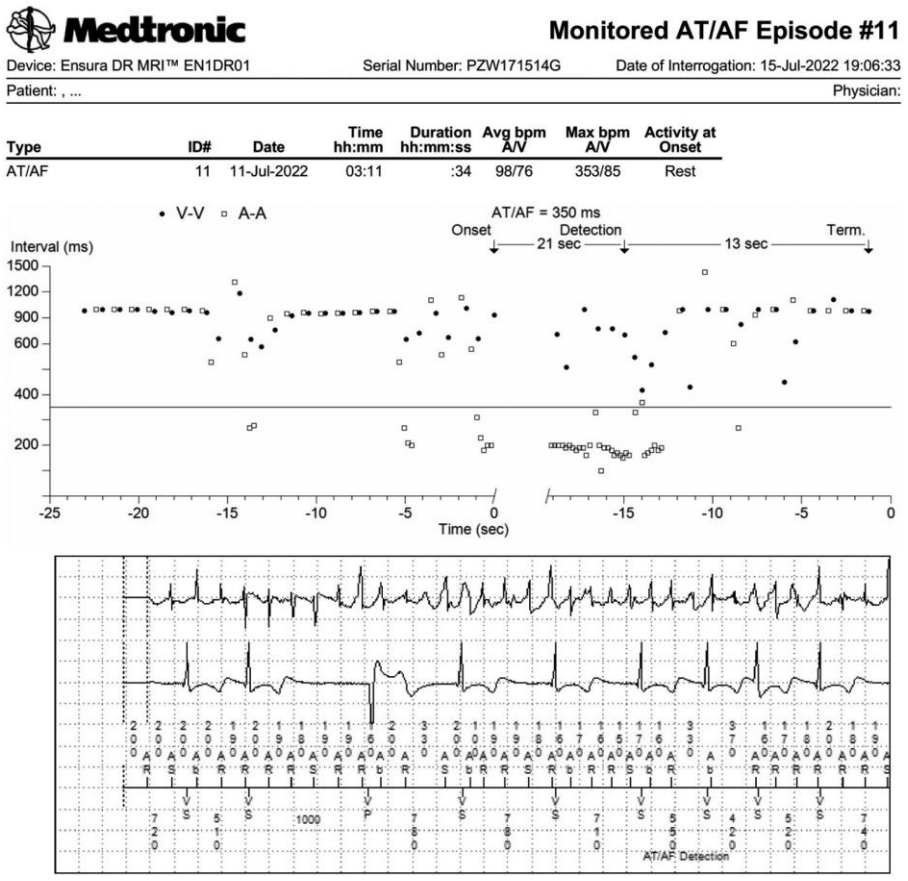

Figure 2. Episode of AHREs in the intervention group: registered on 11 July 2022 and detected on 15 July 2022.

Table 3.

Detection of arrhythmias in the month of their onset, n (%)

Match between month of arrhythmia detection and actual onset	11 Transmissions			Transmissions in 1, 2, 3, 4, 6, 8, 10 and 12 Months		
	Control Group (n=53)	Test Group (n=39)	p-value	Control Group (n=53)	Test Group (n=39)	p-value
Coincide	15 (28.3)	39 (100)	p<0.001	15 (28.3)	34 (87.18)	p<0.001
Do not coincide	38 (71.7)	0 (0)		38 (71.7)	5 (12.82)	

DISCUSSION

According to the results of our study, no significant difference was observed in the frequency of arrhythmia detectionbetween remote telemetry and conventional in-clinic monitoring among elderly patients following dual-chamber pacemaker implantation. These findings are consistent with those reported by A.S. Menezes Junior et al. (2023), who demonstrated that among patients followed up either remotely or in person over a 12-24 month period after pacemaker implantation, atrial tachyarrhythmias were more frequently identified via remote telemetry (OR = 1.22, 95% CI: 1.01-1.48, p = 0.04), whereas no statistically significant differences were found between groups in all-cause mortality, stroke, cardiovascular hospitalisations, or quality of life [17].

Conversely, J. Jiang et al. (2023) found that the detection of AHREs in patients with implanted ICD or CRT devices was associated with more than a twofold increased risk of cardiovascular events and all-cause mortality [18]. It is important to note that the methods used to detect arrhythmias (in-clinic follow-up or remote monitoring) do not influence the occurrence of rhythm disturbances themselves. If an arrhythmic episode occurs, it can be identified by either method - the key difference lies in the timing of detection.

Due to the limited sample size and relatively short follow-up period of the present study, it did not assess endpoints such as mortality, hospitalisation rates for acute coronary syndromes or cerebrovascular events, or their associations with AHREs or remote telemetry.

While remote monitoring was initially considered more critical for patients with ICD or CRT devices - particularly due to risks such as inappropriate shocks or the early detection of ineffective heart failure therapy [10, 19, 20] - recent data underscore its relevance for patients with implanted pacemakers as well. For example, the COMPASS trial reported significantly fewer hospitalisations due to atrial arrhythmias and strokes in the remotely monitored group ($p < 0.05$) [21], while the REFORM study demonstrated a 63.2% reduction in clinic visits among patients receiving remote follow-up [11].

Despite early expectations, randomised controlled trials and meta-analyses evaluating the impact of remote monitoring on overall survival have been largely neutral, although they have consistently shown a reduction in planned hospital visits and associated costs [10, 22]. In the present study, the number of in-person clinic visits among the remote monitoring group was reduced by at least 39 consultations, equivalent to a cost saving of 72,840 RUB.

Some studies have reported improved survival outcomes in patients with implanted devices who underwent remote follow-up [23]. Consistent with prior findings [4, 8], our results demonstrated that arrhythmias were detected significantly earlier in patients from the remote monitoring group.

To our knowledge, no cost-effectiveness studies evaluating remote monitoring in patients with pacemakers have been conducted in Russia. However, a study by Japanese researchers found that remote telemetry was more cost-effective than in-clinic monitoring in this patient population, particularly among those with a CHA_2DS_2-VASc score ≥3, where the benefits of earlier detection and management are likely to be more pronounced [24].

To date, only international publications have evaluated the effectiveness of hybrid monitoring (a combination of remote and in-clinic follow-up). For instance, a joint statement by the Canadian Cardiovascular Society and the Canadian Heart Rhythm Society recommends that, in clinically stable patients, routine in-person follow-up visits should alternate with remote data transmissions via RM) in a 1:1 ratio [25]. However, it is emphasised that clinics should adopt a more flexible and individualised approach, with the 1:1 ratio serving as a general guideline.

In their 2018 study, M. Wah et al. assessed the cost-effectiveness of hybrid monitoring (alternating remote and in-clinic visits at a 1:1 ratio) and found that, among patients with implanted pacemakers, this model was less costly (yielding an additional cost saving of USD 2,370 per patient) and more effective (with a gain of 0.12 quality-adjusted life years) compared to in-clinic follow-up alone [11]. Moreover, public reimbursement for remote monitoring could result in USD 14 million in savings over five years [11]. Similar findings were reported in a study by F.J. García-Fernández et al. (2019), further supporting the cost-effectiveness of hybrid follow-up [26].

Thus, remote monitoring should not fully replace in-person follow-up, but rather serve as a complementary approach, particularly in large, sparsely populated regions of Russia where RM holds significant potential.

An Italian study involving 209 patients with dual-chamber pacemakers compared the cost and effective-

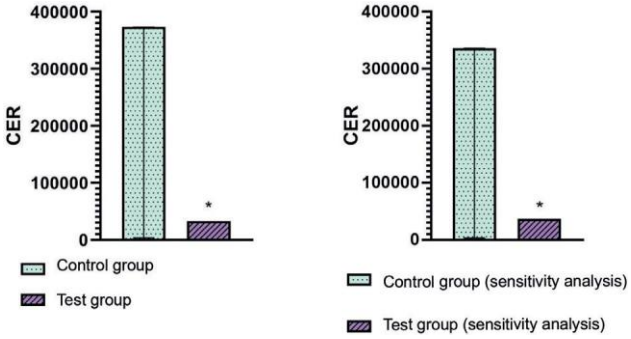

Figure 3. Cost-effectiveness analysis (left) and sensitivity analysis (right) for the scenario with 11 transmissions. *p < 0.05 compared to the control group.

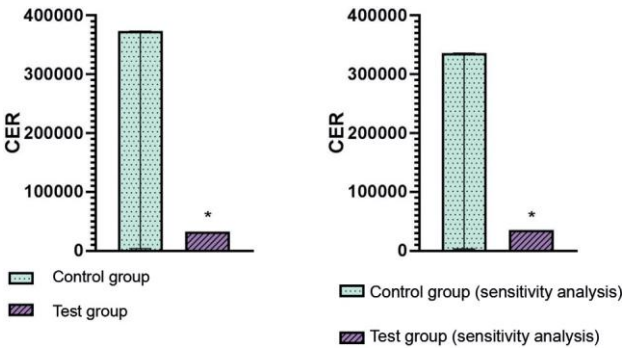

Figure 4. Cost-effectiveness analysis (left) and sensitivity analysis (right) for the scenario with transmissions performed in months 1, 2, 3, 4, 6, 8, 10, and 12. *p <0.05 compared to the control group.

ness of RM versus standard in-clinic follow-up. Annual per-patient costs were significantly lower in the RM group (€56.87 ± 80.22) compared to the standard care group (€169.49 ± 80.22; $p < 0.001$). Hospitalisations in the RM group were reduced by 58.78%, contributing further to cost savings, while quality of life did not differ between the two groups [27].

South Korean researchers calculated the average cost of medical care per minute over a 12-month period before and after the implementation of RM by dividing total healthcare expenditures by the total time spent delivering care per patient. The introduction of RM resulted in a 44% reduction in per-minute medical care costs ($p < 0.001$) [28].

According to the American College of Cardiology and HRS consensus on remote monitoring of CIEDs, data transmission should be performed at least every four months [29]. Current Russian guidelines do not address age-specific considerations or the need for more frequent transmissions in older patients. However, this appears particularly relevant given the higher comorbidity burden and cardiovascular risk in the elderly, warranting more frequent monitoring.

It should be noted that many economic evaluations do not account for the initial costs of implementing RM systems (e.g., equipment purchase) [13]. Moreover, important factors such as patient travel costs, lost workdays, and fall-related risks in the elderly were not included in this study due to the complexity of quantifying such variables and the potential to overburden the design. Nonetheless, future Russian studies should address these aspects as they appear highly relevant and timely.

The RM schedule proposed in this study (months 1, 2, 3, 4, 6, 8, 10, and 12 post-implantation) may contribute to future research evaluating the clinical and economic value of RM in patients with dual-chamber pacemakers in Russia.

While RM may offer a cost-effective solution for most clinics, its feasibility must be assessed locally. For example, RM-enabled devices are used in 58.5% of cases in North and South America, but less than 6% in Asia, likely due to regulatory and economic factors [31]. International data on the cost-effectiveness of RM in pacemaker patients remains inconsistent [13]. However, the present single-centre study demonstrated that RM is economically more viable, a conclusion further supported by deterministic one-way sensitivity analysis.

The lack of clear reimbursement criteria for physicians remains a barrier to the widespread adoption of this promising approach in routine Russian practice. Meanwhile, financial incentives have been shown to increase RM uptake [32]. Further studies are needed to maintain a balance between the increased workload for healthcare providers and the clinical and economic benefits of remote monitoring.

Study Limitations

Clinical effectiveness was assessed based on a surrogate endpoint, without consideration of final clinical outcomes. As the criterion for clinical effectiveness of patient monitoring, the timely detection of arrhythmias (AHRE, AF, AFL, SVT, VT) in the intervention and control groups was used. Detection was regarded as timely if the month of actual onset of the arrhythmia coincided with its identification. A discrepancy between the actual onset and detection of arrhythmia was interpreted as an almost complete loss of diagnostic effectiveness.

The study did not include an evaluation of other economic factors that could have influenced the overall results (e.g. transportation costs, loss of income due to hospital visits, and similar indirect expenses).

Information on the cost of the equipment required for remote monitoring was provided by the manufacturer, Medtronic, USA.

The sample size was determined based on the availability of MyCareLink monitors (model 24950, USA) for remote data transmission, due to existing logistical constraints at the time that prevented expansion of the study cohort.

CONCLUSION

The use of remote monitoring in elderly patients following dual-chamber pacemaker implantation over a one-year period did not reveal statistically significant differences in the incidence of arrhythmias. However, arrhythmias were detected at significantly earlier stages in the intervention group. The cost-effectiveness analysis conducted demonstrated that RM is associated with lower financial costs per unit of effectiveness compared to conventional in-clinic follow-up.

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