

Remote monitoring in elderly patients with chronic heart failure after pacemaker implantation

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Aim. To evaluate the impact of remote telemetry monitoring on the course of chronic heart failure (CHF), functional status, and quality of life (QoL) in patients over 60 years of age after dual-chamber pacemaker (PM) implantation.

Material and methods. This prospective study included 95 patients (49.5% male), mean age 72.5 ± 7.9 years. The main group of patients ($n=40$) was remotely monitored using the CareLink Network remote monitoring system (Medtronic, USA). Data transmission was performed monthly for one year. The control group ($n=55$) underwent in-person clinical follow-up at 1 month and 1 year after surgery. The study and control groups were comparable in age, sex, nosological forms, clinical and demograph-

ic characteristics, and indications for surgery ($p>0.05$). CHF course was assessed using clinical and instrumental parameters, and QoL was assessed using the Minnesota Living with Heart Failure Questionnaire (MLHFQ).

Results. The study found no difference in hospitalization rates based on the follow-up method ($p>0.05$). A significant improvement in the clinical status score was observed in the entire cohort ($p<0.001$). The 6-minute walk test distance significantly increased in the remote monitoring group ($p=0.011$) compared to the control group ($p=0.229$). Quality of life according to the MLHFQ significantly improved in both groups one year after surgery ($p<0.001$). However, the reduction in the total score and

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the subscales “Economic aspects” and “Emotional aspects” was significantly greater in the remote monitoring group ($p=0.002$; $p=0.014$; $p<0.001$, respectively).

Conclusion. In patients over 60 years of age with CHF, pacemaker implantation leads to a significant improvement in clinical status, functional status, and quality of life, regardless of the subsequent follow-up method. At the same time, a significant increase in the 6-minute walk test distance after one year was achieved only with the use of remote monitoring, indicating its advantage in improving exercise tolerance. Comparable hospitalization rates and no changes in echocardiographic parameters in both groups confirm the efficacy and safety of remote follow-up.

Keywords: heart failure, pacemaker, quality of life, remote monitoring.

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Introduction

Chronic heart failure (CHF), despite recent advances in pharmacological treatment, retains its status as a serious disease requiring constant dynamic monitoring and control. An effective mechanism for improving the accessibility of care for patients with CHF, ensuring rapid response to changes in condition, and enhancing treatment adherence is remote monitoring (RM) [1]. Modern cardiology employs a wide range of RM technologies, from comprehensive telephone support to complex implantable systems that transmit physiological data [2–4].

It is known that long-term right ventricular pacing negatively affects left ventricular function, contributing to the development of heart failure, especially in patients with concomitant cardiovascular diseases [5, 6], and worsens the prognosis. Implantation of a biventricular pacemaker (PPM), by addressing dyssynchrony, improves the pumping function of the heart [7].

However, the effectiveness of RM in improving clinically significant outcomes in patients with CHF remains a subject of debate, and data from randomized clinical trials are conflicting [8, 9]. For example, a meta-analysis by Ezimoha et al., summarizing the results of 15 studies, did not reveal a statistically significant effect of RM on mortality but demonstrated a reduction in heart failure-related hospitalizations [8]. At the same time, a review by Calvanese et al. showed that modern multiparametric telemonitoring algorithms integrated with implantable devices can improve clinical outcomes in patients with implantable cardioverter-defibrillators (ICDs) and cardiac re-

synchronization therapy (CRT) devices through early detection of decompensation [9]. Such variability in results may be related to differences in study design, monitoring frequency, technologies used, and patient populations [1].

Current research focuses on analyzing the performance of complex implanted devices (ICD/CRT) in patients with severe systolic dysfunction [10, 11]. At the same time, the value of simpler and more accessible forms of RM (e.g., based on regular interviews and transmission of basic parameters) for patients after implantation of standard dual-chamber pacemakers, who also constitute a large group at risk for the development and progression of CHF, especially in the elderly, remains significantly less studied.

Aim of the study. To evaluate the impact of remote telemetric monitoring on the course of CHF, functional status, and quality of life in patients over 60 years of age after implantation of dual-chamber pacemakers

Material and methods

This work is a prospective single-center study involving 95 patients of both sexes after primary implantation of a dual-chamber pacemaker at the Department of Surgical Treatment of Complex Cardiac Arrhythmias and Electrostimulation.

The study included patients over 60 years of age with second- or third-degree atrioventricular blocks or sick sinus syndrome.

The main and control groups were comparable in age, sex, nosological forms, clinical and demographic characteristics, indications for surgery (Table 1), as well as in all groups of medications taken (angio-

Table 1. Clinical and demographic characteristics of patients included in the study

Parameter	Study group (n=40)	Control group (n=55)	p
Age, years, M±SD	73.20±6.89	72.02±8.53	0.472
Sex, n (%)			0.457
Male	18 (45.0 %)	29 (52.7 %)	
Female	22 (55.0 %)	26 (47.3 %)	
Body mass index, kg/m², Me [Q1; Q3]	28.06 [25.77; 30.84]	27.04 [24.33; 29.91]	0.187
Body surface area, m², Me [Q1; Q3]	1.95 [1.83; 2.06]	1.96 [1.85; 2.00]	0.818
Underlying disease, n (%)		0.267	0.267
—Atrioventricular block, n (%)	24 (60.0 %)	39 (70.9 %)	
—Sick sinus syndrome, n (%)	16 (40.0 %)	16 (29.1 %)	
Comorbidities, n (%)			
Coronary artery disease, n (%)	39 (97.5 %)	53 (96.4 %)	1
Hypertension, n (%)	40 (100.0 %)	52 (94.5 %)	0.261
Angina pectoris, n (%)	4 (10.0 %)	11 (20.0 %)	0.257
Myocardial infarction (MI) in history, n (%)	6 (15.0 %)	10 (18.2 %)	0.785
CHF, n (%)			
Functional class (FC) 1	2 (5.0%)	9 (16.4 %)	0.218
FC 2	14 (35.0 %)	20 (36.4 %)	
FC 3	23 (57.5 %)	26 (47.3 %)	
FC 4	0 (0 %)	0 (0 %)	
Stroke in history, n (%)	3 (7.5 %)	2 (3.6 %)	0.647
Diabetes mellitus, n (%)	11 (27.5 %)	9 (16.4 %)	0.189

Note. [Q1; Q3]—interquartile range; p—significance level; SD—standard deviation.

tensin-converting enzyme inhibitors, sartans, beta-blockers, mineralocorticoid receptor antagonists, sodium-glucose cotransporter 2 inhibitors, diuretics) (p>0.05).

The first group of patients (n=40) constituted the main group. Patients in this group were given a monitor for remote data transmission “CareLink Network” (Medtronic, USA) and were instructed on how to use it. The transmitted information included: periodic intracardiac electrogram data, number and type of detected arrhythmias, percentage of atrial and ventricular pacing, estimated battery life of the pacemaker, and pacing thresholds for both channels.

Patients in the control group (n=55) were followed up in person at the clinic one month after implantation and then again after one year.

The dynamics of CHF were assessed before surgery and after 1 year based on the Clinical Status Assessment Scale (CSAS) for CHF patients, the 6-minute walk test (6MWT), and echocardiography (EchoCG) data. Quality of life (QoL) was assessed using the Minnesota Living with Heart Failure Questionnaire (MLHFQ) before surgery, at 5 days, 1 month, and 1 year after surgery. The number of hospitalizations related to CHF and other causes was evaluated.

The research was approved by the Local Ethics Committee (Protocol No. 9 dated March 11, 2024).

All patients participating in the study confirmed their consent by signing an informed consent form.

Statistical analysis

Statistical analysis was performed using StatTech v. 4.10.4 (developer: Stattech LLC, Russia). Data were described using the median (Me) and lower and upper quartiles (Q1–Q3). Comparison of two groups for a quantitative variable whose distribution differed from normal was performed using the Mann–Whitney U-test. Differences were considered statistically significant at p<0.05.

Results

Data obtained during the 12-month follow-up showed no deaths in the study. When analyzing other cardiovascular endpoints depending on the group, the frequency of hospitalizations was comparable (Table 2). There was no statistically significant difference in the causes of hospitalization (Table 3).

In the study group, there were 5 patients with two or more hospitalizations. The first patient had two hospitalizations related to paroxysmal supraventricular tachycardia (on days 122 and 181). The second had a hospitalization for hypertension on day 30 and for supraventricular tachycardia on day 210. The third had two hospitalizations with a diagnosis of enceph-

Table 2. Number of hospitalizations depending on the group

Parameter	Categories	Group		p
		Study group	Control group	
Hospitalization, n (%)	Yes	11 (27,5 %)	13 (23,6 %)	0,669
	No	29 (72,5 %)	42 (76,4 %)	

Note. p—significance level.

Table 3. Causes of hospitalization depending on the group

Parameters	Categories	Group		p
		Study group	Control group	
Stroke, n (%)	No	39 (97,5 %)	52 (94,5 %)	0,636
	Yes	1 (2,5 %)	3 (5,5 %)	
MI, n (%)	No	40 (100,0 %)	54 (98,2 %)	1,000
	Yes	0 (0,0 %)	1 (1,8 %)	
ACS, n (%)	No	36 (90,0 %)	51 (92,7 %)	0,717
	Yes	4 (10,0 %)	4 (7,3 %)	
CHF decompensation, n (%)	No	39 (97,5 %)	52 (94,5 %)	0,636
	Yes	1 (2,5 %)	3 (5,5 %)	

Note. p—significance level.

alopathy (days 178 and 365). The fourth had a hospitalization for acute coronary syndrome (ACS) on day 146 and for acute cerebrovascular accident (ACVA) on day 268. The fifth had a hospitalization in the rehabilitation department on day 60 and a hospitalization for ACVA on day 302.

In the control group, there were 3 such patients. The first patient—hospitalization for ACS on day 267 and for a newly diagnosed atrial fibrillation on day 370. The second patient—hospitalizations for CHF on day 32 and for ACS on day 360. The third patient—three hospitalizations in the rehabilitation department (on days 60, 120, and 360).

When analyzing the relationship between QoL according to the MLHFQ and the presence of repeated hospitalizations, we failed to identify statistically significant indicators either in the overall patient sample or in the control group ($p > 0.05$).

At the same time, in the remote monitoring group, a significant association was found between an increased risk of rehospitalization and lower (worse) QoL scores: for the total score—at all follow-up time points (5 days, 1 month, and 1 year after surgery); “Economic Aspects”—at 5 days and 1 month; “Emotional Aspects”—at 1 month and 1 year after surgery.

When analyzing the dynamics of CSAS scores in all patients, a statistically significant improvement was

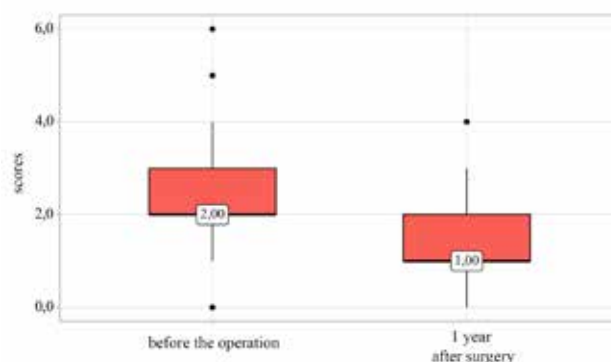


Fig. 1. Analysis of the dynamics of CSAS scores among all patients in the study

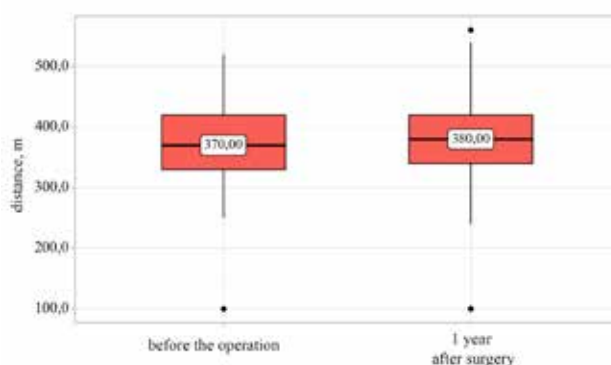


Fig. 2. Analysis of the dynamics of 6MWT results among all patients in the study

revealed between the pre-operative stage [2.0 [2.0–3.0]] and 1 year later [1.0 [1.0–2.0]] ($p < 0.001$). The results are presented in Figure 1.

The analysis showed that in all patients, regardless of the presence of rehospitalizations, there was a statistically significant improvement in clinical status ($p < 0.001$). Similar data were obtained when dividing into the study and control groups ($p < 0.05$).

When analyzing the dynamics of CSAS scores in the study and control groups, similar results were obtained: a statistically significant improvement was found between the pre-operative stage [2.0 [2.0–3.0]] and 1 year later [1.0 [1.0–2.0]] ($p < 0.001$).

When analyzing the dynamics of 6MWT results, a statistically significant improvement was found between the pre-operative stage [370.0 [330.0–420.0]] and 1 year later [380.0 [340.0–420.0]] ($p = 0.007$) among all patients in the study. The results are presented in Figure 2.

In the study group, when analyzing the dynamics of 6MWT results, a statistically significant improvement was found between the pre-operative

Table 4. Echocardiography parameters over time before surgery and 1 year after surgery

Parameter, Me [Q1; Q3]	Before surgery	1 year after	p
LA diameter, cm	4.1 [3.9–4.5]	4.1 [3.9–4.5]	0.423
RA diameter, cm	3.9 [3.7–4.2]	4.0 [3.7–4.4]	0.122
LV EDD, cm	5.4 [5.0–5.5]	5.3 [5.0–5.5]	0.56
LV ESD, cm	3.5 [3.2–3.6]	3.5 [3.2–3.7]	0.58
RV diameter, cm	2.6 [2.4–2.8]	2.6 [2.5–2.8]	0.079
LVEF, %	62.00 (60.00–65.00)	61.00 (60.00–64.00)	0.443
Mitral valve regurgitation, grade	2.0 (1.0–2.0)	2.0 (1.0–2.0)	0.694
Tricuspid valve regurgitation, grade	2.0 (1.0–2.0)	2.0 (1.0–2.0)	0.989
Aortic valve regurgitation, grade	1.0 (0.0–1.0)	1.0 (0.0–1.0)	0.827

Note. [Q1; Q3]—interquartile range; p—significance level.

stage [375.0 [320.0–440.0]] and 1 year later [397.5 [340.0–430.0]] ($p=0.011$), compared with the control group, where no statistically significant changes were found ($p=0.229$). An analysis of the dependence of hospitalizations on the distance walked by patients during the 6MWT was performed, and in the group of patients without rehospitalizations, a statistically significant improvement in the 6MWT indicator was noted ($p=0.004$).

When analyzing echocardiography data without dividing into groups, no statistically significant differences were obtained (Table 4).

An analysis of intergroup differences at the pre-operative stage and 1 year after surgery was performed. No statistically significant changes were found for any parameters except for the size of the right atrium before surgery and at 1 year.

When analyzing the MLHFQ scores, it turned out that there was an improvement in well-being according to the “Total” score: before surgery, the median was 21.00 points (13.00–30.50), at 5 days—14.00 points (10.00–24.00), at 1 month—14 points (8.00–20.00), at 1 year—12 points (7.00–19.50). The differences were statistically significant at all stages compared to the pre-operative period ($p<0.001$).

It was also found that patients in the study and control groups had significant differences at the pre-operative stage in the total QoL score and the “Economic Aspects” and “Emotional Aspects” subscales. For them, an analysis of the absolute increase/decrease in questionnaire scores was performed (Table 5).

Table 5. Changes in quality of life according to the Minnesota Living with Heart Failure Questionnaire over 1 year of follow-up

Parameter	Group	V0-V1	V0-V2	V0-V3
Total score	Study group	-4.00 [-5.00; -2.00]	-4.00 [-6.00; -2.00]	-9.00 [-14.00; -6.00]
	Control group	-3.00 [-6.50; -1.00]	-5.00 [-9.50; -2.00]	-4.00 [-10.50; 1.00]
	p	0.900	0.338	0.002
Economic aspects	Study group	-1.00 [-2.00; -1.00]	-1.50 [-3.00; -1.00]	-3.00 [-5.00; -2.00]
	Control group	-1.00 [-3.00; 0.00]	-2.00 [-4.00; -0.50]	-2.00 [-4.00; 0.50]
	p	0.386	0.349	0.014
Emotional aspects	Study group	-1.00 [-2.00; 0.00]	-1.00 [-2.00; 0.00]	-3.00 [-4.25; -1.00]
	Control group	-1.00 [-2.00; 0.00]	-1.00 [-2.50; 0.00]	-1.00 [-3.00; 1.00]
	p	0.407	0.927	< 0.001

Note. [Q1; Q3]—interquartile range; p—level of statistical significance; V0—QoL assessment before surgery; V1—QoL assessment 5 days after surgery; V2—QoL assessment 1 month after surgery; V3—QoL assessment 1 year after surgery. Statistically significant differences ($p < 0.05$) are highlighted in bold.

It was found that both in the total QoL score and in individual subscales, there was a decrease in the number of points, indicating an improvement in QoL. When analyzing by groups, it was found that the study group had a statistically significantly greater decrease in the total score and the “Economic Aspects” and “Emotional Aspects” subscales after one year compared to the control group ($p=0.002$; $p=0.014$; $p<0.001$, respectively).

For the “Physical Capacity” subscale, in which the groups were initially comparable, over the entire study period, a statistically significant improvement in QoL was found in both the study and control groups ($p<0.001$).

Discussion

The conducted study allows for a comprehensive assessment of the impact of remote monitoring on the course of CHF and QoL in elderly patients after implantation of dual-chamber pacemakers.

At the same time, we did not find statistically significant differences in the frequency of hospitalizations between the study and control groups (27.5% vs. 23.6%; $p=0.669$). The structure of hospitalization causes was also comparable. This suggests that RM, at least in this study, did not lead to a greater reduction in hospitalization rates compared to standard in-person follow-up. This result is consistent with the meta-analysis that summarized data from 15 studies,

which also did not reveal a significant effect of RM on mortality, but differs from the data of the HERO study, in which patients with pacemakers under remote monitoring showed a reduction in unplanned healthcare contacts, although the overall hospitalization rate remained comparable [8, 11]. However, it is important to note that in our study, the study group had more patients with two or more hospitalizations (5 vs. 3), which may indicate a more complex patient population or more active detection and hospitalization of decompensated conditions.

Our study showed a significant decrease in CSAS scores one year after surgery compared to the pre-operative level in the entire patient cohort ($p < 0.001$) and separately in each group, confirming an objective improvement in clinical symptoms of CHF after pacemaker implantation regardless of the follow-up method. A significant increase in 6MWT distance after one year was observed both in the overall patient sample ($p = 0.007$) and separately in the study group ($p = 0.011$), which confirms the literature data on better adaptation to physical activity after device implantation [12]. A possible explanation for the results obtained is that regular RM contributed to better treatment adherence.

Echocardiography did not reveal significant dynamics of key indicators of cardiac structure and systolic function one year after surgery, neither in the overall group nor when divided into study and control groups. These data are similar to the results of the single-center COMMIT-HF study with 822 patients [13].

The improvement in QoL in our study is consistent with the long-term results of LopezVillegas et al., who observed a sustained positive effect of remote monitoring on quality of life and patient satisfaction with implanted pacemakers over five years [14].

Furthermore, the identified relationship between lower QoL scores (total score and "Economic" and "Emotional Aspects" subscales) and an increased risk of rehospitalization in the study group is of interest. These data may indicate that subjective assessment of well-being, especially in the economic and emotional spheres, can serve as a predictor of decompensation in patients under remote monitoring.

Conclusion

Pacemaker implantation in patients over 60 years of age is accompanied by a statistically significant improvement in clinical status, functional status, and quality of life, regardless of the follow-up method. At the same time, a significant increase in 6MWT distance over the year was recorded only in the remote monitoring group, highlighting the advantage of remote monitoring in terms of exercise tolerance. The comparable hospitalization rate and the absence of significant dynamics in echocardiographic parameters in both groups allow considering remote monitoring as an effective and safe approach to managing this category of patients.

Study Limitations. Only one questionnaire was used to assess quality of life; data transmission was performed using a single specific telemetry system ("CareLink Network," Medtronic, USA); effectiveness and patient acceptability may vary depending on the technological platform and interface used; the follow-up period was 1 year, which does not allow assessing the long-term impact on prognosis, structural changes in the heart, and the sustainability of functional status improvement.

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