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Adherence to the treatment of patients in the long-term supervision period after myocardial infarction (according to the REGATA register)

Aim	To study long-term compliance with treatment in patients included into the REGistry of pATients after myocArdial infarction (REGATA).
Material and methods	In 2012–2013, the study included 481 patients with a history of myocardial infarction (MI) who visited the district outpatient clinic. Median age was 72 [62;78] years; men, 51.4% (n=247); median time from the last MI to the date of inclusion into the registry was 5 [2;9] years. Compliance with treatment was determined with the Morisky-Green questionnaire during telephone contacts with patients at 36 and 48 months (n=230) after the inclusion. Patients scored 4 were considered compliant; patients scored 3 were low-compliant; and patients scored 0–2 were non-compliant. Statistical significance of differences in compliance at 36 and 48 months was assessed with the McNemar test.
Results	There were no significant differences between the proportions of compliant, low-compliant and non-compliant patients for the analyzed period. However, at 48 months after the inclusion, the number of patients who had difficulties in answering the questionnaire questions significantly increased from 15.5% to 21.6% (p=0.04). Analysis of changes in compliance with the treatment for only compliant patients showed that at 36 months from the inclusion, 87 patients remained highly compliant (37.8%) while at 48 months, only 32 (36.8%) patients remained compliant with the treatment. Proportion of compliant patients did not significantly differ for men and women, patients younger and older than 60 years, patients with primary MI and reinfarction, prone and not prone to self-management, and for those who used or not the medicine assistance.
Conclusion	The data obtained as a part of the REGATA registry indicate insufficient long-term compliance with the treatment of after-MI patients with both primary MI and reinfarction, an increasing proportion of patients who are unable to assess their degree of compliance, and decreasing compliance among highly compliant patients during the period between 36 and 48 months of observation. On the whole, there were no significant changes in the compliance with the treatment for 12 months between the first and the second interviews. The proportion of patients compliant with the prescribed drug therapy was significantly lower in the presence of predisposition to self-management.

Keywords	Long-term compliance; registry; REGATA; myocardial infarction
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Recent years have witnessed a fall in cardiovascular mortality in developed countries and the reduced contribution of cardiovascular diseases (CVDs) to the overall mortality worldwide. The number of years of partial or complete CVD-related disability is steadily on the increase, as well as the economic damage associated with this group of diseases [1, 2]. Coronary artery disease (CAD) is the leading cause of disability in Europe, accounting for 10% of all years of disability [3]. Costs associated with CAD are dominant (40%) in the structure of CVD-related economic damage in the Russian Federation (RF), European countries, and the United Kingdom, in terms of nosologies [2, 4–6]. These costs are mainly due to the increased number of x-ray guided endovascular interventions, in both acute and chronic CAD [7], as well as the cost of conservative in-hospital management due to failure of outpatient drug therapy [4].

CAD treatment efficacy can be enhanced not only by bringing drug therapy into line with current clinical guidelines, i.e., improving physicians' compliance with the guidelines [8] and patients' adherence to treatment, which as has been shown by previous studies is insufficient [9–11]. In the study by Garganeeva et al.,

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a 5-year follow-up of a small sample of patients with a history of reference myocardial infarction (MI) showed that treatment adherence had more significant effects in the post-infarction period than the compliance of the administered therapy with the clinical guidelines [12].

At the same time, a significant number of studies on adherence in patients with MI therapeutic adherence indicate that poor adherence causes adverse outcomes [13, 14] focusing on the need to develop improvement measures. One of the possible measures is the free provision of drugs to patients. This increases treatment adherence by 4–6%, which is statistically significant, but does not have the expected favorable effect on the prognosis [15]. Concerning patients with MI in the RF, an order of the Ministry of Healthcare #1NB «On approving of the list of medicines for human to be provided for outpatient administration within one year for persons who have suffered acute cerebrovascular accidents, myocardial infarction, and who have undergone coronary artery bypass grafting, angioplasty with stenting, and catheter ablation for cardiovascular diseases» dated January 9, 2020 [16] has been issued. Assessment of the effectiveness of this measure will be determined over time by comparing compliance and outcomes in patients before and after 2020. However, this order regulates preferential drug provision for patients within the first year after MI, and the risks of adverse outcomes remain high in this group and for a long time.

For this reason long-term treatment adherence is of great interest in modern cardiology, and the development of the improvement methods is a promising objective.

This article presents the data on long-term treatment adherence in patients included in the prospective outpatient registry of patients with a history of myocardial infarction (REGATA).

Objective

To study the long-term treatment adherence in patients included in the registry of patients with a history of myocardial infarction (REGATA).

Material and methods

In 2012–2013, the study included 481 patients with a history of MI of any duration and who sought medical attention for any reason in one of the three local outpatient clinics of the Ryazan region (two city clinics and one rural clinic). Patients who were not permanent residents of Ryazan or the Ryazan region were excluded from the study. The median age of patients was 72 [62; 78] years, and male subjects accounted for 51.4% (n=247). 21.8% (n=105) of patients had recurrent MI, and the number of recurrent MI episodes ranged from 2 (70.4%) to 7 (1.0%). The median period from the last MI episode was 5 [2;9] years before inclusion in the registry. The relevant ethics committee approved the study.

Treatment adherence level was determined using the Morisky-Green test after the telephone survey of patients in 36 and 48 months after inclusion [17]. Patients obtained one point for each negative response to the questions. Patients who had 4 points («no» to all four questions) were considered adherent, patients who had 3 points (response «no» to any three questions) were poorly adherent, those who obtained 0–2 points (response «no» to one or two questions or only positive responses) were non-adherent.

Statistical data processing was performed using Microsoft Excel 2007 and STATISTICA 10.0. Data on the frequency of the indicators is presented as a percentage. Data on the time of the patient survey first mentioned in the text is presented as a median and interquartile range (25^{th} and 75^{th} percentiles), and followed as the median. Data on patient contact times first mentioned in the text is presented as a median and interquartile size (25^{th} and 75^{th} percentile), later as a median. Two groups, not linked by a qualitative feature, were compared using contingency tables and Pearson's or Yates's χ^2 and Fisher's exact test, if at least one of the analyzed features occurred less than 10 and 5 times respectively. The differences were statistically significant at $p<0.05$. McNemar's test was used to assess the statistical significance of patient adherence differences at 36 and 48 months. The odds ratio (OR) adherence in 48 months versus 36 months, and the corresponding 95% confidence interval (CI) were also evaluated.

Results

At 36 [36;36] months after the inclusion of patients in the registry, 336 adherence questionnaires had been completed; 52 (15.5%) questionnaires were incomplete; and at 48 [48;48] months, 305 questionnaires, of which 66 (21.6%) were incomplete. Two hundred and thirty patients had fully completed adherence questionnaires at 36 and 48 months. The median age of these patients was 72 [61; 77] years, and 53.5% (n=123) of subjects were male. 22.6% (n=52) of patients had a history of recurrent MI.

The percentages of highly adherent, poorly adherent and non-adherent patients did not differ to a statistically significant degree in the period analyzed, but the number of patients who found it challenging to complete the questionnaire significantly increased from 15.5% to

Table 1. Changes in compliance of patients with a history of MI and enrolled in the registry

Patient groups	At 36 months*	At 48 months*	p
Highly adherent, % (n)	37.8 (87)	31.7 (73)	0.19
Poorly adherent, % (n)	24.4 (56)	23.9 (55)	0.91
Nonadherent, % (n)	37.8 (87)	44.4 (102)	0.17

*, the median duration of the follow-up period from the inclusion date to the dates of the first and second surveys.

21.6% (p=0.04) within 36–48 months after the inclusion. Data on patient adherence and relevant changes is presented in Table 1.

The results obtained reflect adherence in the entire group of patients analyzed, as a whole at this particular time.

Changes in individual adherence, including over a certain time, were also analyzed in the above groups. For example, the analyses produced different data including changes in adherence only among highly adherent patients. At 36 months after inclusion, 87 patients were highly adherent, and at 48 months, only 36.8% (n=32) of them were highly adherent with 18.4% (n=16) having become poorly adherent and 44.8% (n=39) non-adherent (Figure 1).

Fifty-six patients were poorly adherent in the 36 months of follow-up, 37.5% (n=21) of them showed improved adherence level after 12 months of follow-up, and 32.1% (n=18) became non-adherent, while 30.4% (n=17) remained poorly adherent. Thus, one in three patients became non-adherent during the 12-months of follow-up of poorly adherent patients (Figure 2).

At 36 months after the inclusion in the registry, 87 patients were non-adherent, 51.7% (n=45) of them remained non-adherent at 48 months of follow-up. Adherence was considered poor in 25.3% (n=22) of cases and patients became adherent in 23.0% (n=20) of cases (Figure 3).

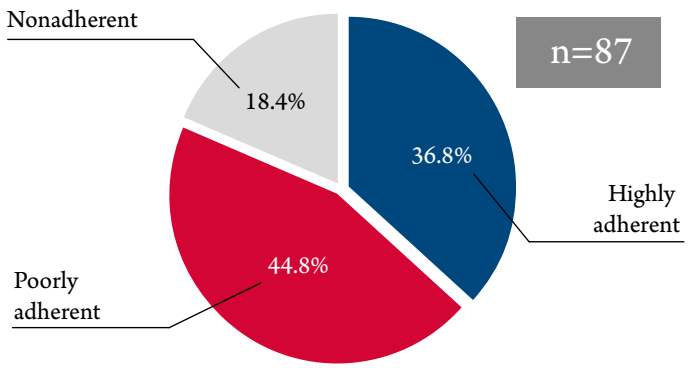
Thus, the comparison of the 36- and 48-month results of the survey revealed that individual treatment adherence was not stable. For example, this was demonstrated by the fact that only 36.5% of patients remained adherent and 23% of non-adherent patients became adherent in 12 months. McNemar's test was used to assess the significance of changes in adherence parameters (Table 2). 36 and 48 month adherence is not correlated, and the changes, as assessed by the Morisky – Green score, are to a greater or lesser extent random.

The data obtained shows no statistically significant differences in adherence according to the surveys in 36 and 48 months after inclusion in the registry.

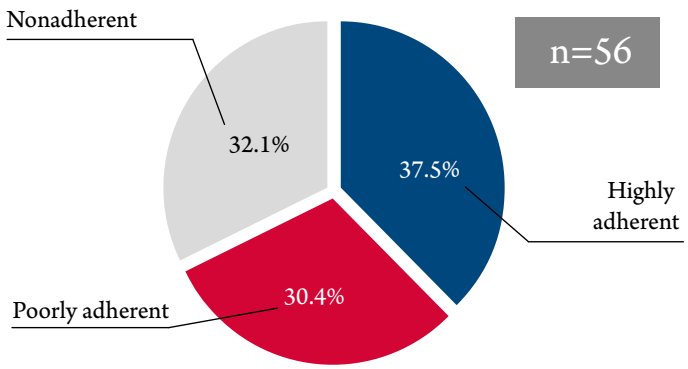
Among male and female subjects, the 36-month treatment adherence was 39.2% (n=48) and 31.7% (n=39), respectively, p=0.69, and the 48-months adherence was 37.4% (n=40) and 30.8% (n=33), respectively, p=0.78. Among subjects under 60 years of age and in the older group, the percentage of adherent patients was 35.2% (n=19) and 38.6% (n=68), respectively, at 36 months (p=0.63) and 38.9% (n=21) and 29.5% (n=52), respectively, at 48 months (p=0.2). Thus, there were no statistically significant differences between the analyzed groups.

The comparison of long-term treatment adherence in patients with primary and recurrent MI showed no statistically significant differences in adherence changes at 36 and 48 months (Table 3). It is noteable that, during the period between the first and second surveys (i.e., 12 months), the percentage of patients with primary MI increased to a statistically significant degree, from 23.0% to 33.1% (p=0.03).

Figures 1. Changes in adherence in highly adherent patients within 48 months of observation



Figures 2. Changes in adherence in poorly adherent patients within 48 months of observation



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53.5% (n=123) of outpatient records indicated that patients received preferential drug provision, and 45.6% (n=105) of patients did not. There was no information about preferential drug provision in 0.9% (n=2) of cases.

The percentage of patients with high treatment adherence among those who received and did not receive preferential drug provision did not differ significantly at 36 months (40.4% vs. 37.1%; p=0.68) and 48 months (36.5% vs. 30.9%; p=0.44) after inclusion in the registry. There were no significant changes in these parameters within 12 months between the first and second surveys (Table 4).

The percentage of male subjects of those who received preferential drug provision was 65.4% (n=34), which was significantly higher than those who did not use this benefit, i.e., 49.7% (n=87); p=0.047. The percentage of female subjects was significantly lower among those adherent to preferential provision of medicines, 34.6% (n=18), than in the comparison group, 50.3% (n=88); p=0.047.

Of 230 patients included in the adherence analysis, 4.4% (n=10) of outpatient records included data on self-medication propensity, 11.7% (n=27) on the absence of such. There was no information about self-medication propensity in 83.9% (n=193) of cases. According to the 36-month survey, 20% (2 of 10) of patients prone to self-medication were treatment adherent, which was significantly less than in the absence of self-medication, 51.9% (14 of 27), p=0.02. However, these differences

Figures 3. Changes in adherence in nonadherent patients within 48 months of observation

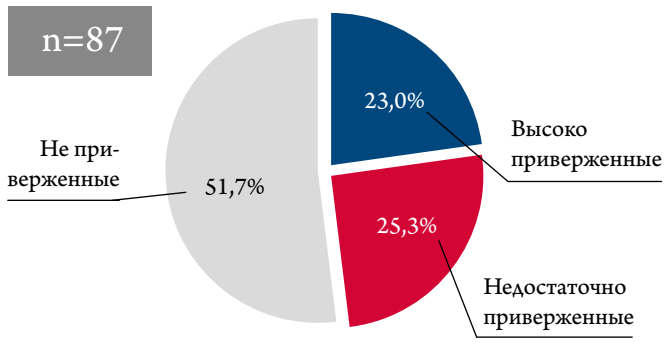

Table 2. Changes in compliance of patients with a history of MI and enrolled in the registry

At 36 months	At 48 months	
	0-3 points	4 points
0-3 points (n=143)	102	41
4 points (n=87)	55	32
All patients (n=230)	157	73

p (McNemar)=0.153; OR=1.34 (95% CI: 0.88; 2.06)

Table 3. Long-term compliance in patients with a history of first-time and repeat MI

Группы пациентов	Patients with first-time MI (n=178)			Patients with repeat MI (n=52)				
	At 36 months	At 48 months	p_{1-2}	At 36 months	At 48 months	p_{3-4}	p_{1-3}	p_{2-4}
	1	2		3	4			
Highly adherent, % (n)	38.8 (69)	32.0 (57)	0.21	34.6 (18)	30.8 (16)	0.72	0.59	0.86
Poorly adherent, % (n)	24.7 (44)	23.6 (42)	0.81	23.1 (12)	25.0 (13)	0.84	0.81	0.83
Nonadherent, % (n)	36.5 (65)	44.4 (79)	0.13	42.3 (22)	44.2 (23)	0.88	0.13	0.98

Table 4. Proportions of patients with high, poor, and low adherence to drug therapy after 36 and 48 months of follow-up in groups of patients who received preferential drug provision and did not

Parameter		Treatment adherence for						p		
		36 months of observation			48 months of observation					
		High	Insufficient	Low	High	Insufficient	Low			
Receiving drug provision		3	4	5	6	7	8	p_{3-6}	p_{4-7}	p_{5-8}
Received, n=52	1	40.4% (21)	23.1% (12)	36.5% (19)	36.5% (19)	23.1% (12)	40.4% (21)	0.69	0.59	0.69
Did not receive, n=175	2	37.1% (65)	24.6% (43)	38.3% (67)	30.9% (54)	24.0% (42)	45.1% (79)	0.21	0.5	0.19
p_{1-2}		0.68	0.82	0.82	0.44	0.73	0.54			

were not statistically significant at 48 months of follow-up: 30% vs. 25.9% (p=0.55).

Discussion

The analysis of data on treatment adherence in patients with a history of MI and included in the REGATA registry is generally consistent with the data obtained in other studies and indicates poor adherence after an acute coronary event. According to different authors, the adherence level differs significantly depending on the presence or absence of a history of MI. Thus, there was no statistical difference in the adherence studies within the registry of cardiovascular diseases (RECVASA) in patients with CAD at two outpatient clinics, the number of the adherent, poorly adherent, and non-adherent patients with exertional angina and patients with a history of MI [18]. The comparison of patients included in the RECVASA registry, who had a combination of chronic heart failure, arterial hypertension, and a history of MI, and patients with a combination of chronic heart failure, arterial hypertension, and CAD who had no history of MI, showed that the percentage of adherent patients was higher in the group with a history of MI, 37.2% vs. 30.6%, (p<0.05) [19]. On the other hand, Nelidova et al. demonstrated that acute MI significantly (3.5-fold) increased patients' adherence [10]. However, it remained low, especially over the long-term. For example, Davidovich et al. [20] showed by means of the Morisky-Green questionnaire that after 2.5 years of follow-up, 47.6% of patients with a history of MI were adherent to the treatment, 24.4% were poorly adherent, 19.7% were non-adherent, while 8.3% of patients found it challenging to complete the test. After a 5-year observation of patients with a history of MI, Garganeeva et al. [12] showed that only 45% of patients with a history of MI strictly followed physician's recommendations for the drug therapy. According to Sedykh et al. [21], recurrent MI increases patients' willingness to fully follow the physician's recommendations after MI from 38% (first-time MI) to 62% (recurrent MI). However, according to our data, this willingness remains unattained. The lower adherence to treatment in patients with recurrent MI can be explained in our study by the fact that Sedykh et al. [21] included patients with acute MI, and the percentage of 62% reflected potential treatment adherence. Our study, contains no information about potential and initial treatment adherence. The adherence itself and its changes are evaluated at 36 and 48 months in surviving patients. It should be noted that adherence to treatment in patients with a history of MI means not only stricter compliance with drug prescriptions but also includes visiting medical institutions, which improves the quality of outpatient drug therapy [22].

Poor adherence in patients with a history of MI at 36 and 48 months after inclusion in the outpatient registry was detected in the groups of patients with both first-time and recurrent MI, in both male and female subjects, regardless of the need for preferential drug provision. This is an adverse fact and requires effective measures to increase adherence in patients with a history of MI during long-term outpatient management. One of such measures may be to improve patient management based on treatment adherence assessment and an assessment of their willingness to administer medications, modify their lifestyles, and regular visits to physicians [23].

Conclusion

The findings of the REGATA registry indicate poor long-term adherence to treatment in patients with a history of myocardial infarction, both first-time and recurrent, regardless of gender, and and increased percentage of patients who are unable to assess their adherence level, and decreased treatment adherence in highly adherent patients over the period between surveys, at 36 and 48 months of follow-up. In general, there were no significant changes in treatment adherence within the 12-month period between the first and second surveys. We discovered that only about half of the patients with a 2–9-year history of MI received preferential drug provision at the outpatient observation stage. The percentage of patients adherent to treatment did not differ significantly, if patients used this benefit or not. Insufficient attention is paid to the propensity to self-medication in some patients, a significantly lower percentage of whom are adherent to drug therapy prescribed by a physician.

No conflict of interest is reported.

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