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## PERCUTANEOUS CORONARY INTERVENTIONS IN PATIENTS WITH ST-ELEVATION MYOCARDIAL INFARCTION: 10-YEARS FOLLOW-UP

<i>Aim</i>	To study long-term results and to identify predictors of death in patients with ST-segment elevation acute myocardial infarction (STEMI) who underwent endovascular revascularization.
<i>Materials and methods</i>	This study included 283 patients registered in the hospital registry of percutaneous coronary interventions (PCI) for STEMI from 2006 through 2009. Analysis of 10-year results included all-cause and cardiovascular death rate, incidence of recurrent myocardial infarction (MI), repeated revascularization, stroke, stent restenosis and thrombosis. Also, a composite endpoint MACCE (Major Adverse Cardiovascular and Cerebrovascular Events) was evaluated, which included death, recurrent MI, repeated PCI, stent restenosis and thrombosis, coronary bypass, and stroke.
<i>Results</i>	Information about the health condition was provided by 204 (72.1%) patients. Mean follow-up period was 120.1±9.5 months. All-cause mortality was 25.5% with cardiovascular death determined in 19.1% of cases. Recurrent MI developed in 21.6% of patients; in 1.5% of cases, recurrent MI resulted from thrombosis of previously implanted stents. Repeated PCI was performed for 31.9% of patients; in 13.7% of cases, the PCI was performed for stent restenosis. Coronary bypass was performed for 5.4% of patients. Incidence of stroke was 10.3%. Major cardiovascular and cerebrovascular complications (MACCE) during the follow-up period were determined in 60.3% patients. According to the Cox proportional hazards regression model, age ≥65 years (odds ratio (OR), 3.75 at 95% confidence interval (CI) from 1.75 to 8.03; p=0.001) and incomplete coronary revascularization (OR, 3.09 at 95% CI from 1.52 to 6.30; p=0.002) were independent predictors of death based on data of the 10-year observation.
<i>Conclusion</i>	Therefore, at 10 years following endovascular revascularization, STEMI patients showed a moderate death rate with a high incidence of major cardiovascular and cerebrovascular complications. The leading causes for fatal outcomes were recurrent cardiovascular complications. The major predictors of death for the coming 10-year period included age ≥65 years and incomplete myocardial revascularization.
<i>Keywords</i>	ST-segment elevation acute myocardial infarction; percutaneous coronary interventions; long-term results
<i>For citation</i>	Bessonov I. S., Kuznetsov V. A., Dyakova A. O., Gorbatenko E. A., Evlampieva L. G., Kicherova O. A. et al. Percutaneous Coronary Interventions in Patients With ST-Elevation Myocardial Infarction: 10-Years Follow-up. <i>Kardiologiya</i> . 2020;60(6):69–75. [Russian: Бессонов И. С., Кузнецов В. А., Дьякова А. О., Горбатенко Е. А., Евлампиева Л. Г., Кичерова О. А. и др. Эндоваскулярная реваскуляризация при остром инфаркте миокарда с подъемом сегмента ST: результаты 10-летнего наблюдения. <i>Кардиология</i> . 2020;60(6):69–75.]
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Percutaneous coronary interventions (PCI) are currently the gold standard for patients with acute ST-segment elevation myocardial infarction (STEMI) [1]. The common clinical use of endovascular revascularization techniques and the establishment of regional vascular centers in the Russian Federation have made a significant contribution to the reduction of mortality from myocardial infarction (MI) and cardiovascular diseases (CVDs) [2, 3]. However, establishing a prognosis for patients and identifying potential predictors

used for the prognosis remain challenging in the clinical setting.

In most studies of long-term outcomes in patients with acute MI, the endovascular reperfusion strategy has been applied in only few patients [4–6]. Only two studies analyzing the results of long-term follow-up of patients with MI after endovascular revascularization were found in the available literature [7, 8]. After 8 years of observations, Barchielli et al. [7] determined that the incidence of major cardiovascular

complications after PCI, including death, MI, and emergency revascularization, was 47.7%. In another study, during the regular employment of endovascular revascularization strategy in acute STEMI for 9 years, mortality ranged from 16.8% to 23.5%, depending on type of coronary stent used [8]. This analysis is relevant due to the absence of similar studies in the Russian population of patients. Accordingly, the objective of this study was to analyze 10-year findings and identify predictors of death in patients with acute STEMI who had undergone endovascular revascularization.

### Materials and methods

The study included 283 patients included in the Register of PCI for acute STEMI of Tyumen Cardiology Scientific Center from 2006 to 2009. In 2016–2019, 10-year outcomes were analyzed. The following algorithm was used to obtain patient information: first, data from the electronic medical records were analyzed to identify repeat hospitalizations and cardiologist visits, telephone calls were made to invite patients for an in-person visit, and if a patient could not visit personally, the patient was surveyed over the telephone. If a patient had been admitted to another hospital during the follow-up period, they were asked to read out the discharged summary during the telephone survey. In several cases, written questionnaires were sent by mail. We verified data from our database against the mortality database of the Tyumen Region Medical Information Analysis Center to increase the significance of the findings.

Blood flow was assessed in the infarct-related artery (IRA) using the Thrombolysis in Myocardial Infarction (TIMI) score before and after PCI in all patients. Angiographic success was defined as the recovery of coronary blood flow (TIMI 3), the absence of mural thrombi in the artery of interest and occlusion of the large lateral branches, grade 3 myocardial blush according to the MBG (myocardial blush grade) score. Analysis of hospitalization outcomes included mortality, the rate of MI recurrence, stent thrombosis, and the no-flow phenomenon (the absence of myocardial perfusion (MBG 0–2 and/or blood flow less than TIMI 3) after the reopening of the infarct-related coronary artery (CA). Moreover, a composite endpoint was used, which was major adverse cardiovascular and cerebrovascular events (MACCE), including death, recurrent non-fatal MI, repeat PCI, restenosis and/or thrombosis of the stent, coronary artery bypass grafting (CABG), stroke.

All interventions were performed through the transfemoral access. All patients received a loading dose of acetylsalicylic acid (150–300 mg), clopidogrel

(300–600 mg) before PCI. Intracoronary injections of nonfractionated heparin 7500 IU were made to all patients during PCI. If necessary, pre-hospital thrombolysis was performed using tenecteplase. If pre-hospital thrombolysis failed, a lifesaving PCI was performed. Pre-hospital thrombolysis was ineffective in the following cases: reduction in ST-elevation less than 50% from the baseline level within 90 minutes, hemodynamic abnormalities, inappropriate electrical activity, and worsening of ischemic symptoms. Time-related data were analyzed in all patients: the duration of the pain syndrome before admission to the hospital, the time from admission to the hospital to the artery reopening (door to balloon time), and in the case of pre-hospital thrombolysis, the time from the onset of pain syndrome to the administration of a thrombolytic agent and the time from the administration of the thrombolytic agent to PCI. Endovascular revascularization was performed on IRA only in the case of two- or multiple-vessel coronary artery disease. Depending on angiographic findings and patient clinical status, either staged PCI or CABG (when patient was stable) was recommended.

The analysis of the 10-year findings included all-cause and cardiovascular mortality, the rate of recurrent MI and repeat revascularization (repeat PCI and/or CABG if they were not scheduled at discharge), restenosis and thrombosis of previously implanted stents, and the rate of strokes. The composite endpoint of MACCE was also estimated, and the number of patients with incomplete coronary revascularization was calculated. Incomplete coronary revascularization was established if stenosis was more than 50% of the vessel diameter and/or in the presence of occlusion of at least one of epicardial CA with a diameter of more than 1.5 mm [8].

Statistical analysis of findings was performed using a statistical software package (SPSS Inc., version 21.0). The results are presented as the mean and the standard deviation ( $M \pm SD$ ) for normal distribution and the median (Me) with the interquartile range (25th percentile; 75th percentile) for asymmetric distribution. The distribution of quantitative variables was estimated using the Kolmogorov-Smirnov test. The Student's t-test was used for the comparison of quantitative variables of the normal distribution, and the nonparametric Mann-Whitney test was used for the non-normal distribution. Pearson's chi-squared test was used to compare categorical variables [22]. The intergroup differences were statistically significant at  $p < 0.05$ . A Cox proportional hazards regression model was used to assess the risk factors of death within the study period. Survival was assessed using the Kaplan-

**Table 1.** Baseline clinical and angiographic findings

Parameter	Number of patients		
	Abs.	%	
Mean age, years (M±SD)	57.1±9.7		
Male	159	77.9	
Smoking	95	46.6	
Obesity	74	36.3	
History of hypertension	164	80.4	
History of DM	32	15.7	
Insulin therapy	16	50	
Chronic kidney disease	2	1	
History of CAD	79	38.7	
History of MI	36	17.6	
History of PCI	17	8.3	
Acute heart failure (Killip class)	I	181	88.7
	II	12	5.9
	III	5	2.5
	IV	6	2.9
Anterior MI	99	48.5	
Pre-hospital thrombolysis	24	11.8	
Primary PCI	180	88.2	
Lifesaving PCI	13	6.4	
Localization of IRA	• LCA	-	-
	• LAD	91	44.6
	• LCCA	34	16.7
	• RCA	75	36.8
	• Diagonal branches	-	-
	• Obtuse marginal branches	5	2.5
	• Intermediate artery	2	1
Nature of the coronary lesion	• Single-vessel	100	49
	• Two-vessel	40	19.6
	• Multivessel	64	31.4
Non-infarct related and hemodynamically significant lesion of LCA	4	2	
Mean number of implanted stents (M±SD)	1.2±0.5		
Direct IRA stenting	82	40.2	
Stents with antiproliferative drug coating	45	23.4	
Time from the onset of pain syndrome to hospitalization, min, Me [25%; 75%]	120 [80; 210]		
Time from hospitalization to PCI, min, Me [25%; 75%]	60 [45; 80]		
Time from the onset of pain to thrombolysis, min (M±SD)	121.7±92.0		
Time from thrombolysis to PCI, min (M±SD)	411.5±230.1		

DM, diabetes mellitus; CAD, coronary artery disease; MI, myocardial infarction; PCI, percutaneous coronary intervention; LCA, left coronary artery; LCCA – left circumflex coronary artery; IRA, infarct-related artery.

Meyer method with Cox proportional hazards and the log-rank test.

## Results

Health information was received from 204 (72.1%) patients during the in-person visit (n=32 [15.7%]) and through the telephone survey or written questionnaire (n =172 [84.3%]).

When analyzing clinical characteristics (Table 1), it should be noted that the majority were male patients of working age. Anterior MI and lesions of the left anterior descending artery made up about half of all cases. The majority of patients had undergone primary PCI. Several patients received pre-hospital thrombolytic therapy. In 13 cases, pre-hospital thrombolysis was ineffective, which required lifesaving PCI. Multivessel coronary lesions were found in more than one-third of patients. Antiproliferative drug-coated stents were implanted in less than one-quarter of all cases, and direct stenting of IRA (without predilation and/or thromboaspiration) was performed in less than 50% of patients.

Hospital outcomes and 10-year follow-up findings are provided in Table 2. In terms of results analysis, it should be noted that mortality was less than 4%. The mean follow-up period was 120.1±9.5 months. During the study period, all-cause mortality was 25.5%. In 75% of all cases, death was caused by CVDs. During the study period, MACCE were reported in more than 50% of patients. Complete myocardial revascularization was not achieved during the study period in one-third of patients.

Table 3 contains data of uni- and multivariate regression analysis of Cox proportional hazards. According to the multivariate analysis, age and incomplete coronary revascularization were the mortality predictors for the forthcoming 10 year period.

Figure 1 demonstrates the Kaplan–Meier analysis of the overall survival of patients, survival by age, and completeness of myocardial revascularization.

At the end of the study period, the cumulative survival rate of patients was 69% (Figure 1A). The cumulative survival rate of patients at the age of <65 years old was 79.2%, ≥65 years old – 37.2% (p<0.001; Figure 1B). The cumulative survival of patients was 82.4% in the group of complete myocardial revascularization and 34% in the group of incomplete revascularization (p<0.001; Figure 1B).

## Discussion

Our findings showed that 10 year mortality rates after endovascular revascularization for acute STEMI were 25.5%. Nonetheless, long-term mortality was

**Table 2.** Hospital and 10-year follow-up outcomes

Parameter	Hospital outcomes		10 year follow-up outcomes	
	Abs.	%	Abs.	%
Death from all causes	8	3.9	52	25.5
Death from cardiovascular causes	8	3.9	39	19.1
Recurrent/repeat nonfatal myocardial infarction	2	1.0	44	21.6
Stent thrombosis	2	1.0	3	1.5
Repeat PCI	2	1.0	65	31.9
Restenosis of the stent	-	-	28	13.7
Coronary artery bypass grafting	-	-	11	5.4
Stroke	-	-	21	10.3
MACCE	10	4.9	123	60.3
Incomplete coronary revascularization	103	50.5	55	27.0

PCI, percutaneous coronary intervention; MACCE, major adverse cardiovascular and cerebrovascular events (death, recurrent nonfatal myocardial infarction, repeat PCI, restenosis and/or thrombosis of the stent, coronary artery bypass grafting, stroke).

**Table 3.** Cox’s proportional hazard regression model showing the effects of variables on mortality within 10 years of follow-up

Parameter	Univariate analysis		Multivariate analysis	
	OR (95% CI)	p	OR (95% CI)	p
Age ≥65 years old	4.09 (2.26–7.41)	<0.001	3.75 (1.75–8.03)	0.001
Male	1.55 (0.69–3.48)	0.289	2.21 (0.93–5.26)	0.074
Smoking	0.62 (0.33–1.14)	0.123	0.92 (0.41–2.07)	0.838
History of DM	0.65 (0.26–1.66)	0.369	0.52 (0.19–0.45)	0.522
History of MI	1.52 (0.77–3.02)	0.227	0.87 (0.39–1.93)	0.865
Multivessel coronary disease	2.04 (1.13–3.70)	0.019	1.16 (0.58–2.32)	0.673
Incomplete revascularization	4.41 (2.43–8.00)	<0.001	3.09 (1.52–6.30)	0.002
Direct IRA stenting	0.75 (0.40–1.39)	0.359	1.04 (0.54–2.01)	0.899
Glucose at admission ≥7.77 mmol/L	0.72 (0.38–1.37)	0.317	0.70 (0.34–1.45)	0.337
Anterior localization of MI	1.22 (0.68–2.21)	0.508	1.05 (0.56–1.97)	0.871
Pharmacoinvasive strategy	0.16 (0.02–1.19)	0.074	0.23 (0.03–1.77)	0.160
Reduced LV contractility	2.04 (1.13–3.70)	0.018	1.14 (0.60–2.16)	0.692

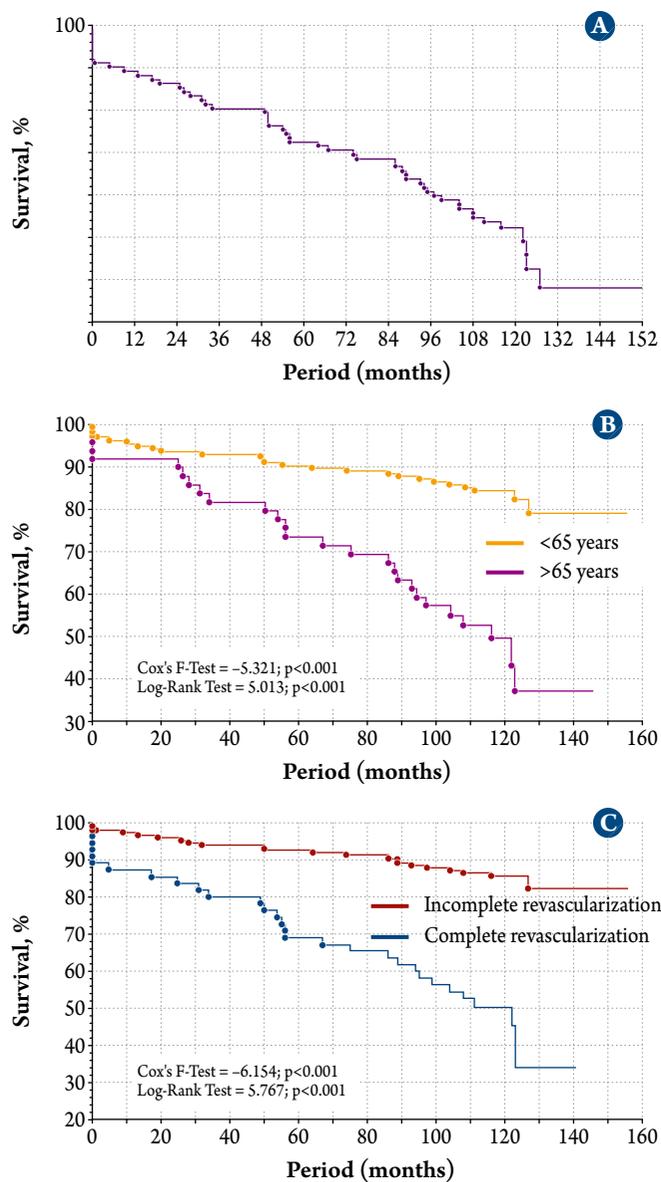
OR, odds ratio; CI, confidence interval; DM, diabetes mellitus; MI, myocardial infarction; LV, left ventricle; IRA, infarct-related artery.

higher in several earlier studies of long-term outcomes after MI. Thus, according to the analysis of the Tomsk Register of Acute MI, 1- and 5-year mortality was 11% and 35%, respectively [4]. In the TACOS study, 10-year mortality in patients with acute STEMI was 52.5% [5]. According to the analysis of the New Zealand Acute Coronary Syndrome (ACS) Register, mortality during the observation period of 10–13.5 years was 58% [6]. It should be noted that the results of the long-term mortality assessment in the above two studies are more than twice as high as our findings.

As for the causes of mortality, the analysis of differences from several previous studies distinguished

two main aspects. First, most patients in these studies had not undergone PCI. For example, the percentage of patient deaths after endovascular revascularization in the TACOS study was only 24%. PCI was common as well in patients included in the New Zealand and Tomsk registers. The low rate of endovascular revascularization strategy in these studies is likely to cause both high hospital (TACOS 9.6%, New Zealand ACS register 14%, Tomsk ACS register 17.1%) and long-term mortality. Barchielli et al. [7] also showed the relevance of endovascular revascularization strategy in their study with an 8-year follow-up of 875 patients with acute STEMI, in which PCI was an independent predictor of

**Figure 1.** Ten-year follow-up survival rate (Kaplan-Meier analysis)



A – survival in the general patient group;  
B – survival depending on the age group;  
C – survival depending on the completeness of revascularization.

a decrease in all-cause mortality (odds ratio [OR] 0.72, 95% confidence interval [CI] 0.59–0.88;  $p = 0.001$ ).

The second-most likely cause of higher mortality in several previous studies was a difference in the age of patients. Plakht et al. [9] showed that the 10-year mortality was 18.5% and 69.7% in patients <65 years old and  $\geq 65$  years old, respectively. It should be noted that the median age at inclusion was 69 [59; 77] years in the TACOS study (Finnish population), 72 [58; 81] years in the New Zealand ACS Register, and 56 [50; 64] years in our study. Mortality rates in older patients are naturally higher. It was confirmed by the results of the regression analysis of Cox's proportional hazards, according

to which the age of  $\geq 65$  years was one independent predictor of death within the 10 year follow-up period. In our study, the proportion of cardiovascular mortality in the total mortality was comparable to that in the TACOS study (75% and 73.9%, respectively) [5].

In several previous studies, in which the endovascular revascularization strategy was regularly applied, 8- and 9-year mortality rates were comparable to those observed in our study [7, 8]. At the same time, the incidence of MACCE was high in our study. It is mostly a consequence of the progression of atherosclerosis, frequent recurrent MI and strokes, and repeat revascularizations. Thus, it is necessary to strictly follow the guidelines for secondary prevention of CVDs and find possibilities to increase patient compliance.

Our findings showed that incomplete myocardial revascularization in patients with acute STEMI is a major predictor of long-term mortality. These data are clinically significant, particularly given that current guidelines for myocardial revascularization in ACS do not cover this issue [1].

The effect of incomplete revascularization on the prognosis was investigated in several studies. For example, in the recent, large randomized COMPLETE study, which included more than 4,000 patients, complete myocardial revascularization in multivessel coronary disease was associated with a significant decrease in cardiovascular mortality and incidence of MI (OR 0.74, 95% CI 0.60–0.91;  $p = 0.004$ ) [10]. The median follow-up period was 3 years. In our study, the positive effect of complete myocardial revascularization was identified in the early follow-up period. However, a progressive decrease in cumulative survival in patients with incomplete myocardial revascularization was observed after 50 months of follow-up. The effect of complete myocardial revascularization after acute STEMI on survival was also shown in several small randomized trials [11–13]. It is important to maintain a time limit between PCI on IRA and other coronary arteries with hemodynamically significant lesions [14]. As for non-infarct related coronary arteries, stage PCI is possible within 45 days after discharge from the hospital [15]. There is no convincing data on a time limit for performing CABG after PCI on the IRA [1].

We have previously identified factors that have significant effects on hospital outcomes for patients with acute STEMI [16, 17]. They include patient age  $\geq 65$  years, elevated glycemia at admission, and the possibility of direct stenting of the IRA. However, multivariate analysis determined no impact of these parameters on the long-term prognosis.

It should be noted that our study has several limitations: First, its retrospective nature and the fact that individual patients were lost to follow-up. We verified our findings against the mortality database of the Tyumen Region Medical Information Analysis Center. It should be noted that some patients may have moved to another region. Moreover, we did not analyze drug therapy or patient compliance in this study. However, poor compliance in patients after MI is a pressing concern. Poor adherence to drug therapy is one of the factors contributing to the recurrence of MI [18].

## Conclusions

In 10 years after endovascular revascularization, moderate mortality rates and high rates of major

cardiovascular and cerebrovascular events were observed in patients with acute ST-segment elevation myocardial infarction. The high rate of such complications was caused by frequent recurrent myocardial infarctions, strokes, and the performance of repeat revascularizations due to the progression of atherosclerosis. Recurrent cardiovascular complications were the leading causes of death. The age of  $\geq 65$  years and incomplete myocardial revascularization were the main predictors of death within the next 10 years.

*No conflict of interest is reported.*

**The article was received on 15/12/20**

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