Abstract

First experience with the use of extra-long (40 to 60 mm) sirolimus-eluting stents in patients with diffuse long coronary lesions

Objectives: To assess the clinical outcome of one year follow-up in patients with diffuse long lesions treated with extra-long sirolimus-eluting stents.

Methods and Results: 85 patients underwent implantation of very long BioMime stents (Meril Life Sciences, India) for the period from March 2014 to February 2016.

Results: The angiographic success rate was 100%, clinical success was observed in 98.8% cases (onepatientdevelopedperiprocedural MI). The additional back-up support for stent delivery was used in 11 (12.9%) patients (the «buddy wire» technique in 6 pts and Guidzilla catheter in 2 pts.).Cumulative MACE rate at 12 months was 9.4% with 1.1% myocardial infarction and 5.9% TLR. One patient died 6 month after stent implantation from massive pulmonary thromboembolism. None of the patients had subacute or late stent thrombosis. Follow-up angiography was performed in 48 (68.5%) patients, 5 (10.4%) patients demonstrated restenoses.

Conclusion: The use of extra-long sirolimus-eluting stents is associated with good procedural and one-year clinical outcomes in complex patients with long and diffuse lesions.

Key words: Percutaneous coronary intervention; diffuse coronary lesions; long drug-eluting stents.

The study of the possibilities of endovascular treatment of patients with complex forms of lesions of coronary arteries (CA) is especially urgent for today [1,2,3]. It is known that about 20% of all performed percutaneous coronary interventions (PCI) occur in patients with prolonged stenoses of SC [4]. In this case, the proportion of patients with diffuse lesions of the coronary bed is steadily increasing and amounts to 40-50% [1]. At present, there are generally recognized criteria for determining diffuse lesions of the coronary bed, which often creates certain difficulties in choosing the optimal method of revascularization of the cardiocardi [2]. Initially, diffuse lesions were used to count stenoses over 20 mm long, but the connection with the development of interventional technologies increased the criteria for the determination [5,6].

Up to now, in the arsenal of interventional cardiologists, there were mainly stents with a length of up to 30-38 mm, which, in the treatment of prolonged coronary artery constrictions, required the implantation of two or more stents "overlapping." It is known that such an approach can be accompanied not only by an increase in frequency and Stent thrombosis, but also the formation of aneurysm arterial dilatations in the stent junction area due to the excessive concentration of the stent-covering drug [7,8]. In recent years, new drug-stent stents with a length of 40-60 mm have appeared on the market of endovascular treatment tools [9]. The first experience of using such stents is positive, however, in the few available studies, the technical features of the procedure, as well as the long-term results of treatment, have not been fully explained and studied [10].

The purpose of this study was to evaluate the immediate and long-term (one-year) results of using very long stents (40-60 mm long) with a drug coating in the treatment of patients with extensive and diffuse lesions of the coronary arteries.

Materials and methods:

During the period from May 2014 to February 2016, 85 patients with stable development of coronary artery disease with coronary angiography (CAG) with diffuse, extended stenoses were included in the study on a prospective basis. The clinical characteristics of patients are presented in Table 1. The average age of

patients was 63.6 ± 9.8 years, 63 (74.1%) were Men. Arterial hypertension was detected in 45 (52.9%) people, smoking - 21 (24.7%), diabetes mellitus - in 20 (23.5%), hyperlipidemia - in 76 (89.4%). In 60 (70.5%) patients in the anamnesis, a myocardial infarction (MI); 5 patients (5.9%) underwent coronary artery bypass grafting, 17 (20.2%) patients had angioplasty with stenting of the SC before. Reduction of contractile function of the left ventricle (PV less than 40%) was observed in 5 (5.8%) patients.

The inclusion criteria were: the presence of at least one stenosis of a QR with a length of ≥40 mm with a degree of constriction ≥50% in diameter in combination with attacks of angina of tension or rest and objective signs of myocardial ischemia on a resting ECG, during a sample with a measured physical load or Holter ECG monitoring .

The study did not include patients with stenosis of the left coronary artery (LCA) ≥ 50%, acute coronary syndrome and multivessel lesions (with a value on the Syntax scale33).

Coronarography:

The procedure was performed by radial or ulnararium access to the AlluraXpera FD10 angiographic unit (Philips, the Netherlands), non-ion-based contrast preparations Ultra-370 (BayerScheringPharmaAG, Germany) and Mallinckrodt (Canada) were used. The degree and extent of arterial stenosis were determined using automatic quantitative coronary analysis using the XceleraR2.2L1SP2 software (Philips, The Netherlands). For calculation, the final diastolic frame was selected in the projection with the maximum degree of stenosis. For calibration, the tip of the diagnostic catheter was used, unfilled with contrast material [11]. In the analysis, the following parameters were determined: the extent of the impact (mm); The reference diameter of the angiographically unchanged section of the artery is proximal and distal to the stenosis (mm); The minimum diameter of the arterial artery (MDAP) (mm) and the degree of stenosis by diameter (%). MDMA and the degree of arterial narrowing were calculated before and after PCI, as well as with

controlled angiographic examination after 12 months. Angiographic carborenosis was defined as artery stenosis more than 50%, revealed in control CAG.

Transilluminal balloon angioplasty (TBA) with stenting CA. All patients underwent PCI with implantation of one long drug-eluting stent (BFS) - BioMime (Meril Life Sciences, India). The third-generation cobalt-chromium platform with a thickness of 65 μm, coated with a thin 2 μm by a layer of a biodegradable polymer based on polylactate-glycolic acid, which provides release of sirolimus for 30 days. Stenting was performed according to the conventional procedure [12]. In all cases, stenosis was pre-dilation, the balloon diameter was selected from the balloon / artery ratio of 0.8-0.9, in the presence of pronounced calcinosis Non-compliant balloons were used. The size of the stent was selected according to the magnitude of the distal reference diameter of the artery. Optimization of proximal stent sections was carried out by non-compliant balloons, their diameter was selected according to the size of the proximal reference segment. For 5-7 days before the intervention, all patients received clopidogrel at a dose of 75 mg per day in combination with aspirin at a dose of 75-100 mg per day. At the beginning of the procedure, intravenous heparin was administered at a rate of 100 U / kg body weight, followed by the determination of the activated clotting time. In the subsequent every 30 minutes, repeated determinations of AST were carried out. To maintain the AST at> 300, if necessary, heparin was re-administered at a rate of 35-50 units / kg body weight. After the procedure, all patients received a double antiplatelet therapy (75 mg aspirin and 75 mg clopidogrel) for 12 months.

The criterion for the immediate success of the intervention was the elimination of narrowing with a residual stenosis less than 20% and the degree of antegrade TIMI-III without the occurrence of complications (death, MI, emergency PCI surgery, CABG) during the hospital period. The long-term results of the study were evaluated in an outpatient examination of patients, As well as for repeated hospitalization. The testimony for the control CAG was a recurrence of the clinic for stenocardia, a positive sample for the detection of latent ischemia of the

myocardium, as well as the noninformativeness of the results of a sample with a dosed physical load or the impossibility of carrying it out.

To evaluate the results of the study, the following endpoints were accepted: death from all causes, death from cardiovascular causes, myocardial infarction, repeated revascularization of the target lesion.

Statistical processing: Continuous variables having a normal distribution were represented as $M \pm \sigma$, where M is the mean and σ is the standard deviation. Continuous variables, the distribution of which differed from normal, represented a median and 25% -75% percentiles. Logistic regression analysis was used to assess the impact of clinical angiographic factors on the incidence of adverse cardiovascular events. To determine the degree of contingency of each of these factors, the Pearson criterion was used. At the same time, the exponential coefficient of the regression equation was used as an estimate of the relative risk associated with the action of the factor. The influence of the predictors included in the model and the accuracy of the whole model were generally considered reliable if the values of p criterion $\chi 2$ were less than 0.05. The statistical analysis was carried out with the help of a package Statistical analysis of SPSS (Chicago, IL, USA).

Results of the study:

Angiographic characteristics of patients are presented in Table 2. According to the CAG data, 26 (30.5%) patients had a single-vessel lesion, 31 (36.4%) patients had a two-vessel lesion and 28 (32.9%) patients had a three-vessel lesion. The major part of lesions that underwent intervention was 45 (52.9%) localized in the right coronary artery (PKA), 30 (35.3%) in the anterior descending artery (PNA), 10 (11.8%) were located in the envelope Arteries (OA). Of the 85 prolonged stenoses subjected to revascularization, 40 (47.1%) lesions accounted for chronic occlusions of the CA, and 47 (55.8%) cases accounted for the bifurcation lesions, of which 12 (255%) were true Bifurcations. In assessing the severity of coronary artery lesions on the Syntax47 scale (55.3%), patients were assigned to the low-risk group

(Syntax≤22 points), and the average risk group (Syntax = 23-32) included 38 (44.7%) Patients. The main part of the procedures was performed in 77 patients (90.6%) through radial, in 8 (9.5%) patients through the ulnar access. According to the results of quantitative angiography, the average length of stenosis was 52.4 ± 9.4 mm, the average value of the reference artery diameter was 3 , 1 ± 0.7 mm, the mean value of the minimum diameter of the lumen of the constriction before the intervention is 0.92 ± 0.5 mm and the degree of narrowing of the interference -60.2 ± 18.7%. During the procedure, 219.9 ± 95, on average, 9 ml x-ray contrast medium per patient (from 80 to 500 ml) (see Table 3). 85 drug-eluting stents were implanted, of which 22 (25.8%) were stents with variable diameter (with "trapezoidal" constriction, In which the diameter of the proximal segment was 0.5 mm larger than the distal segment.) The number of stents 40 mm long was 16 (18.8%), 25 (29.4%) had a length of 44 mm, 24 (28.2%) - 48 mm. The number of stents with a length of 50 and 60 mm was 10 (11.8%) and 10 (11.8%), respectively (Fig. 1).

The immediate angiographic success of the intervention was 100%, the immediate success of the procedure was 98.8% (1 patient was diagnosed with type 4a MI). Technical difficulties in the stent to the place of stenosis appeared in 11 (12.9%) patients. To overcome them, in 6 (7.1%) the technique of the "additional conductor" ("buddywire") was used, in 2 (2.3%) a deep intubation of the guide catheter was performed, in 1 (1.2%) the method of "anchoring "In the lateral branch with an inflated balloon catheter. In 2 (2.3%) patients, in connection with the ineffectiveness of standard techniques for stenting, additional GuideZilla extension catheters (BostonScientific, USA) were used.

The average period of observation of patients included in the study was 12.6 ± 2.5 months. 8 (9.4%) of cases (Table 4) were observed at the frequency of the combined index of large cardiovascular events, including death, myocardial infarction, and repeated revascularization of the target lesion. During the observation, one patient died suddenly of massive pulmonary embolism (autopsy was performed at the place of residence) , 1 (1.2%) patient underwent MI, repeated

revascularization of the target lesion was performed in 6 (7.1%) patients, there were no cases of late thrombotic occlusions of the stent. The survival rate without major cardiovascular events 1 year after the procedure was 91.6 % (Figure 2).

The control CAG was performed in 48 (68.5%) patients, the average percentage of stented segment stenosis was 21.5 ± 3.2%, the minimum diameter of the stentablenium was 2.46 ± 0.4 mm, the late lumen loss was 0.18 ± 0.2 Mm. Angiographic restenosis (narrowing more than 50% of the diameter of the artery) occurred in 5 of 48 patients with control CAG, which was 10.4% (Table 5). When conducting a binary logistic regression, there was no correlation between clinical and angiographic characteristics and long-term PCI. Factors such as age and sex of the patient, smoking, diabetes, hypertension, hyperlipidemia, chronic occlusion, diameter and length of the stent in our study did not affect the development of cardiovascular complications (table 6).

Discussions:

It is known that PCI of complex forms of CA lesions is associated with a decrease in the immediate success of the procedure and a high incidence of unfavorable cardiac complications [11]. In our work, it was shown that the use of very long stents with a drug coating (> 40 mm) in the treatment of diffuse and extended CA lesions allows in most cases to achieve good immediate and long-term results with a low level of cardiac complications. The immediate success of the procedure was 98.8%, while the overall incidence of adverse cardiovascular events was 1.2%. Only 1 patient was diagnosed with MI development without a Q 4 type tooth in the hospital period.

After the introduction of the drug-eluting stents into clinical practice, considerable progress was made in the treatment of this category of patients [13]. In a multicenter randomized trial, LONG-DESIII (PercutaneousTreatmentof LongNativeCoronaryLesionsWithDrug-ElutingStent-III), a comparative analysis was made of the use of everolimusisyrolimusclosed stent patients with prolonged stenoses (≥25 mm). [14] At the 9th month of follow-up, the incidence of

angiographic restenosis in the everolimus-covered stent group was 7.3% And 2.7% in patients in the sirolimus-coated stent group (p = 0.04); The late loss of lumen inside the stented segment was 0.22 ± 0.43 mm in comparison with 0.18 ± 0.28 mm, respectively (p = 0.29). According to the meta-analysis, combining the results of large trials of SPIRIT, XIENCE V, out of 323 patients with long SV lesions (≥35 mm) after implantation of everolimus-coated stents, in the long-term follow-up period the incidence of cardiac complications was 9.2%, the frequency of re-revascularization of the target lesion was -8.9%, while the frequency of late stent thrombosis was 1.6% [2]. Serious concerns today are associated with a high risk of developing late thrombotic occlusions after SLP implantation, which may be due to delayed endothelialization of the stent, as well as an increase in the extent of the stented segment of the SC [14]. In a large register, SuJ. Et al., In which 3,157 patients were included after implantation of sirolimus and everolimus-coated stents, an increase in late stent thrombosis with an extent of lesion of> 31.5 mm was noted. [15] In these studies, the technique of stenting of long lesions by several stents using the " "(" Overlapping "), as in the market of instruments at the time there were no stents longer than 40 mm. Vulnerable to this technique is the "joint" of the stents, which due to a double layer of metal in this area is the cause of excessive hypertension neointima, and the allocation of a double dose of a cytotoxic drug is the cause of the formation of aneurysmal expansions [16]. Polymer coatings of 1 generation, due to delayed endothelialization and increased risk of late thrombosis, prompted researchers to find new ways to solve the problem.

Stents with a drug coating of a new generation with a fully biodegradable polymer based on polylactic acid are now developed [9,10]. In our work we used a stent with a biodegradable polymer coated with sirolimus - BioMime (Meril Life Sciences, India). The complete release of the drug from the surface of the stent takes place after 30 days, and the complete resorption of the polymer from polylactate acid - after 40-50 days. In the results of our one-year follow-up, the overall mortality was 1.2% of cases; The frequency of repeated revascularization

of the target lesion is 7.1%, the incidence of restenosis is 10.4%; Late loss of lumen inside the stent - 0,18 ± 0,2 mm. The cases of subacute and late thrombosis were stenting. It should be noted that at the moment there is a small number of publications evaluating the long-term results of implantation of very long stents (> 40 mm). In the study of Polavarapu RS and the co-author of 258 patients after implantation of sirolimus-coated stents, with a biodegradable polymer 40 mm long in a remote observation period, the combined frequency Cardiac complications was 2%, which was comparable to the results of our work-2.2% [10].

In the literature there are not enough consecrated questions concerning the occurrence of complications, technical features of PCI for diffuse lesions of SC. In our work, technical difficulties occurred during stent placement to the site of stenosis in 11 (12.9%) patients, in spite of the fact that in most cases guide tubes with extraback-up EBU, XB, AL were used. Extended stenoses in addition to the standard technique of strengthening the support of the guide catheter ("buddywire", deep intubation of the guide catheter, the technique of "anchoring") in 2 cases, we used the new guide-extension guides-GuideZilla (BostonScientific, USA). The Hydraulic Extender is a soft-tip monorail catheter compatible with a 0.014-in. Coronary conductor. A flexible distal part (25 cm in length) allows a deep intubation of the artery with the overcoming of technically complicated artery sections [18].

It is known that a number of clinical and morphological factors, such as diabetes mellitus, smoking, chronic CA occlusion, the length of the lesion increase the technical complexity of the endovascular procedure and the risk of complications in the near and distant periods [19,5]. In the regression analysis, we did not find a correlation between the incidence of cardiac complications in the long-term period and clinical-angiographic factors. This may be due to a relatively small sample, as well as a low percentage of cardiovascular events.

At the same time, the use of very long stents to treat patients with prolonged stenoses of the coronary arteries potentially can reduce the economic costs of the procedure by reducing the number of implantable stents.

Conclusion.

The use of very long sirolimus-coated stents (40-60 mm) to safely and effectively prolong the extensive lesions of the coronary arteries according to a one-year observation is accompanied by a low risk of repeated revascularization of the target lesion and the development of other adverse cardiovascular events.

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Table 1. Clinical characteristics of patients included in the study (n = 85).

Index	**N**	**%**
Middle age, years	63.6±9.8	
The Men	63	74.1
Women	22	25.9
Smoking at the moment	21	24.7
Arterial hypertension	45	52.9
Hyperlipidemia	76	89.4
Diabetes	20	23.5
Peaks	60	70.5
Previously transferred PCI	17	20.2
Previously transferred CABG	5	5.9
LVEF <40%	5	5.9

PEAKS - Post-infarction cardiosclerosis; KS-coronary bypass surgery; LVEF - left ventricular ejection fraction

Table 2: Angiographic characteristics of patients (n = 85).

Index	**n**	**%**
Total number of stenoses	85	100
Type of blood supply of the myocardium		
Right	59	69,4
Left	12	14,1
Balanced	**14**	**16,5**
Number of affected arteries		
1	26	30,5
2	31	36,4
3	28	32,9
Localization		
PHA	30	35,3
PCA	45	52,9
OA/ATC	10	11,8
Chronic occlusions	40	47,1
Bifurcation stenosis	13	15,2
Score on the Syntax scale (points)		
Low risk (≤22)	47	55,3
Average risk (23-33)	38	44,7

Table 3: Initial quantitative angiographic and procedural data, n = 85.

Characteristics	**n**	**%**
Extent of initial lesion, mm	52.4±9.4	
Reference diameter of the artery, mm	3.1±0.7	
Minimum diameter of lumen narrowing, mm:		
Before the procedure	0.92±0.5	
After the procedure	2.64±0.2	
Degree of stenosis (%)		
Before the procedure	60.2±18.7	
After the procedure	17.1±5.6	
Vascular access during PCI		
Radial	77	90.6
Ulnarny	8	9.5
Time of procedure (min)	39.8±19.9	
The dose of irradiation (mGy)	1934.8±740.5	
Time of X-ray irradiation (min)	14.5±6.2	
The average volume of contrast in-va for 1 patient (ml)	219.9±95.9	

Table 4: Remote clinical outcomes of PCI in 12 months (n = 85).

Characteristics	**n**	**%**
Combined endpoint	8	9.4
Death from all causes	1	1.2
Cardiac death	0	0
Myocardial infarction	1	1.2
Repeated revascularization of target lesion	6	7.1

*Death from all causes + IM + revascularization of the target lesion.

Table 5: Quantitative angiographic data after 12 months (n = 48).

Characteristics	**n**	**%**
Minimum diameter of lumen stent, mm	2.46±0.4	
Average degree of stenosis,%	21.5±3.4	
Late loss of lumen diameter, mm*	0.18±0.2	
Angiographic carcinogenesis,%	5	10.4
Late thrombosis of the stent	0	0

* Calculated as the difference between the minimum diameter of the artery lumen after stent implantation and after 12 months.

Table 6: Evaluation of the effect of predictors of cardiovascular complications (binary logistic regression, n = 48)

Clinical and angiographic factors	**OSH (95% CI)**	**p***
Age	2.27 (0.39-13.12)	0.35
Floor	1.60 (0.25-10.07)	0.61
Smoking	2.0 (0.21-18.95)	0.54
Diabetes	0.47 (0.07-3.01)	0.42
Hyperlipidemia	0.91 (0.82-0.99)	0.43
PCI, CABG in history	1.41 (0.15-13.62)	0.76
LVEF	1.12 (0.22-5.97)	0.88
Chronic occlusion	0.62 (0.49-0.78)	0.06
Stent length, mm	0.68 (0.74-6.12)	0.72
Diameter of the stent, mm	0.79 (0.86-7.22)	0.83

CI - confidence interval; CABG - aortocoronary bypass; LVEF - left ventricular ejection fraction

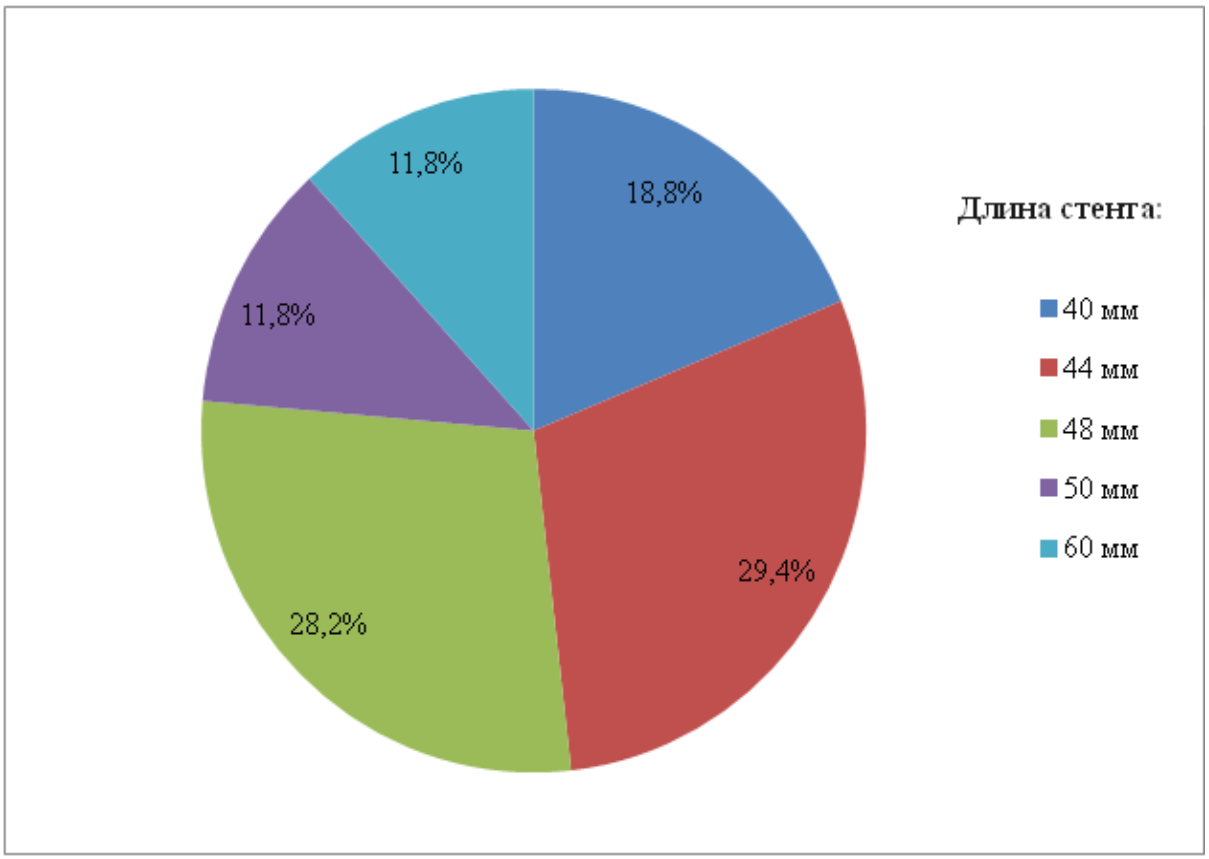


Figure 1: Distribution of stents along the length (n = 85)

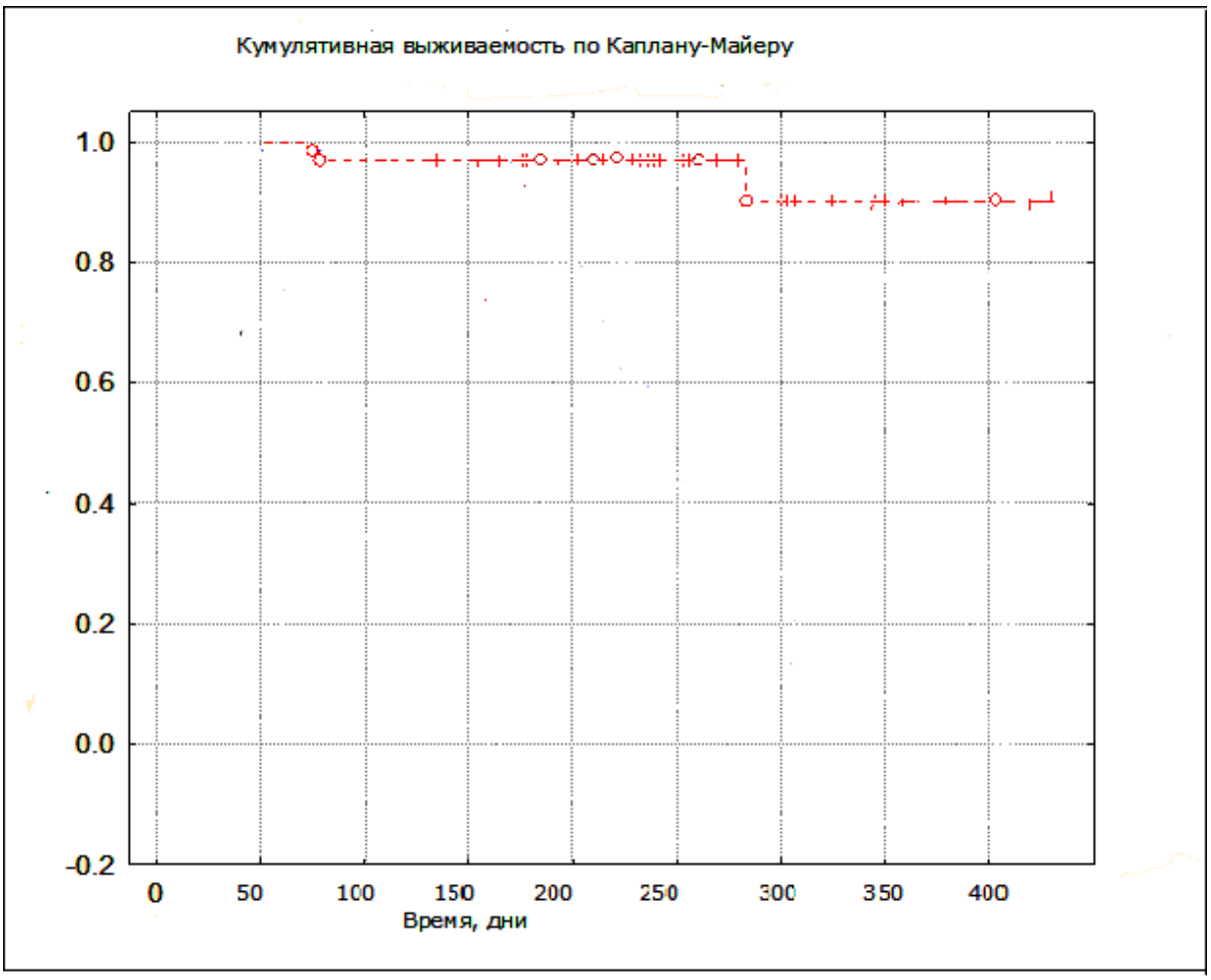


Figure 2: Survival curve (Kaplan-Mayer) without cardiovascular events in patients with diffuse coronary arteries.

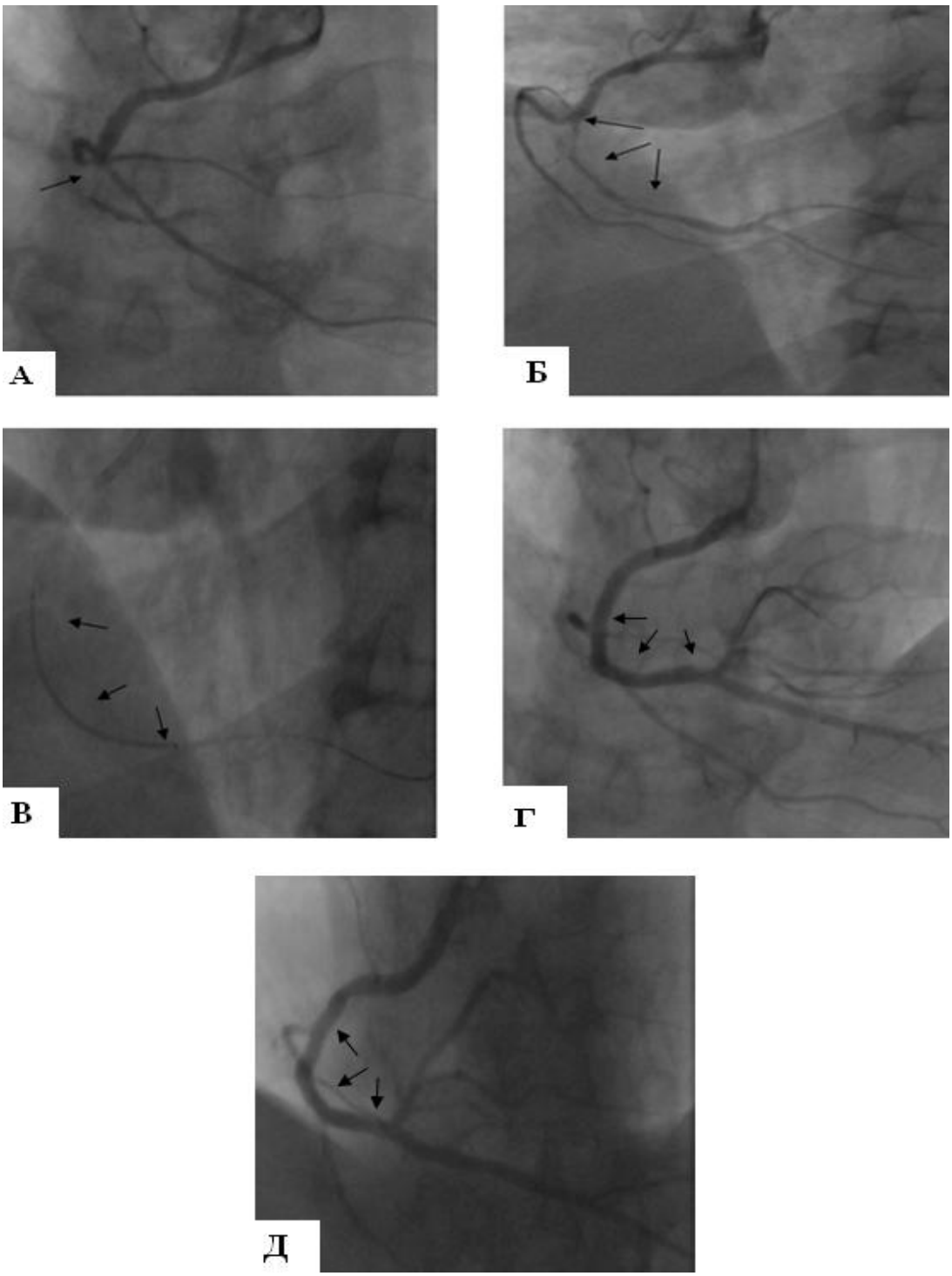


Figure 3: Angiograms of the patient H., 52 years old. A - the initial angiogram, the arrow indicates subtotal stenosis on the verge of occlusion, the degree of antegrade blood flow TIMI 2 (according to TIMI classification); B - after predilatation with balloon 2.5x20 mm, arrows indicate extended residual stenosis of middle segment of right coronary artery (PKA), B - The stage of positioning the stent BioMime 3.0x48 mm, indicated by arrows; T-final result (after stent implantation), no residual stenosis; E-control angiogram of the APC at 12 months, the stented segment is passable, with no signs of restenosis (indicated by arrows).

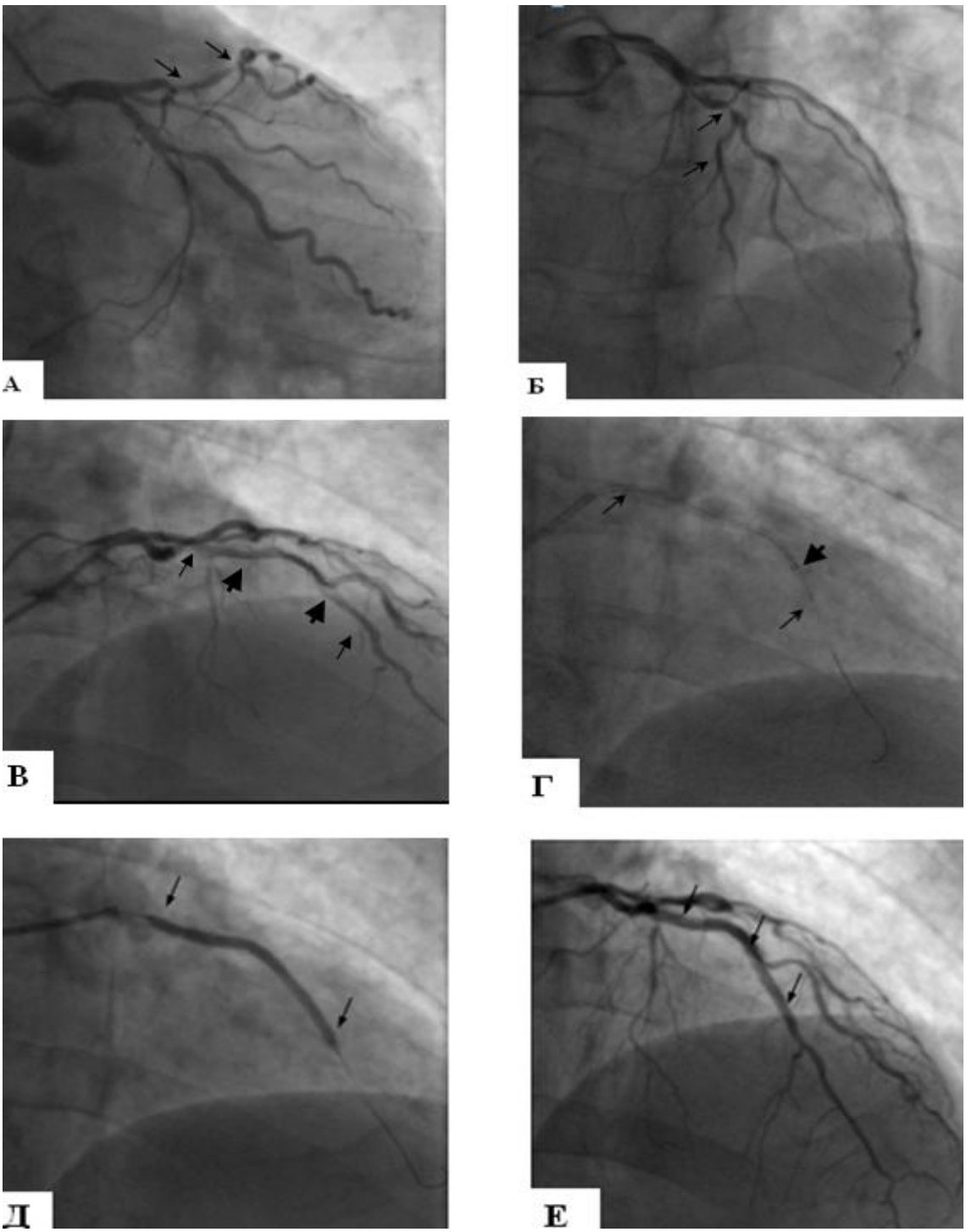
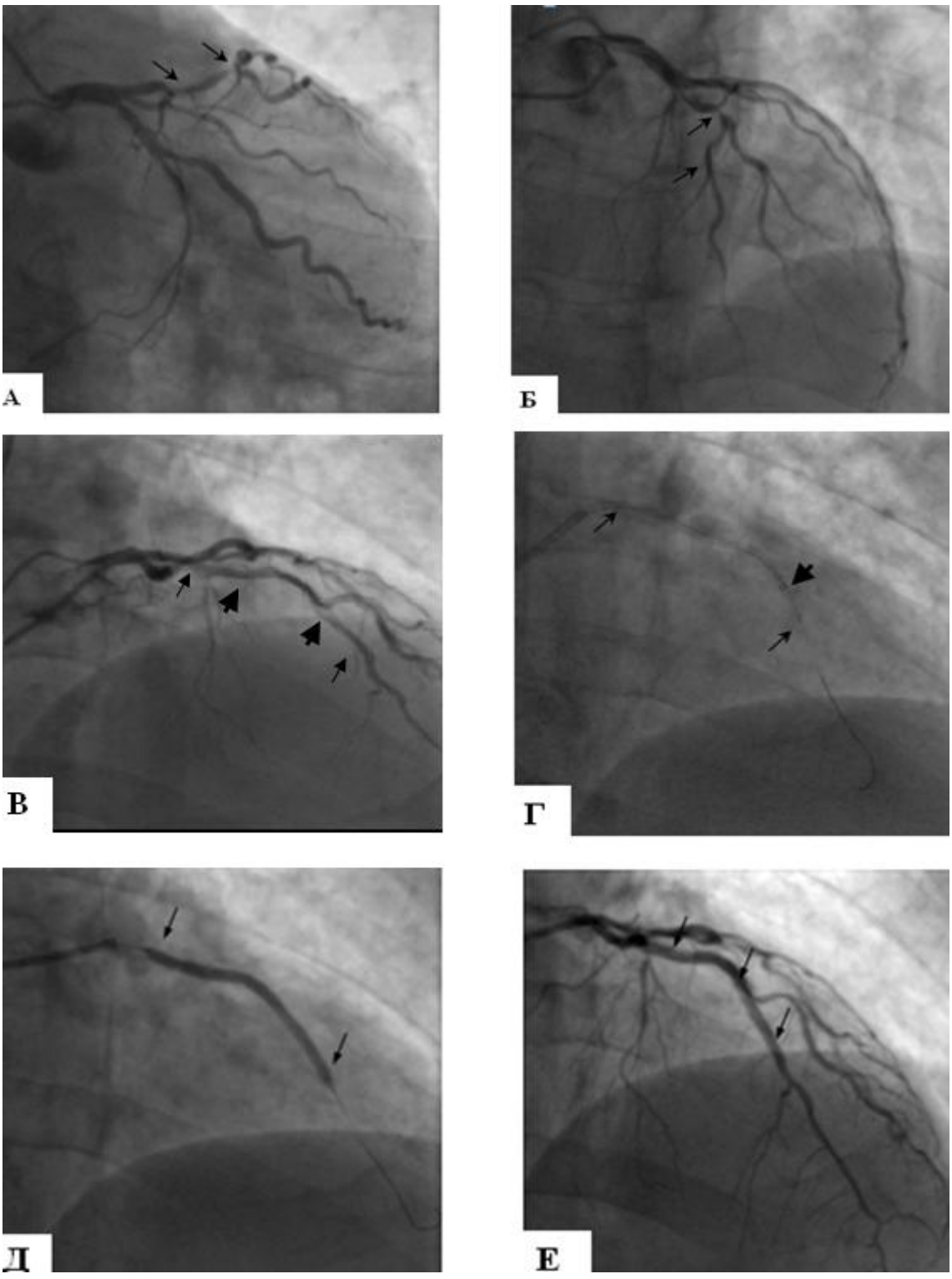


Figure 4: Angiograms of the patient G., 74 let.A., B-source angiograms, arrows indicate diffuse, extended lesion of anterior descending artery (PNA); B - after predlatation balloons2.5x15 mm and 2.5x30 mm, the usual arrows indicate extended residual stenosis of the proximal and middle segments of the PNA, bold arrows indicate a dissection that has arisen after the predilatation, G - holding the stent in the middle segment of the PNA with the aid of the GuideZilla extender, The arrow shows the tip of the GuideZilla catheter in the middle segment of the PNA, the usual arrows indicate the stents of the stent BioMime 3.0x48 mm; D-implantation of the stent after removal of the GuideZilla catheter (indicated by arrows); E-end result, arrows indicate stented segment, residual stenosis is absent.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