DOI: 10.23934/2223-9022-2019-8-1-45-52

Endovascular Treatment with Limus Eluting Stents in Patients with Acute Coronary Syndrome

M.V. Chernyayev*, A.G. Faybushevich, Y.S. Muzganova

Department of Advanced Surgery with a Course of Pediatric Surgery
Peoples' Friendship University of Russia
6 Mikluho-Maklaya St., Moscow 117198, Russian Federation

*** Contacts:** Mikhail V. Chernyayev, Physician for X-ray Endovascular Methods of Diagnosis and Treatment, postgraduate student of the Department of Advanced Surgery with a Course of Pediatric Surgery, PFUR. Email: mikhailcherniaev@mail.ru

BACKGROUND Coronary artery disease is one of the main causes of the population's disability and mortality in Russia and abroad. Revascularization with coronary stents in the course of the most suitable drug therapy is one of the most important treatments of coronary artery disease. It is essential to pay special attention to the research results of using modern stents, in particular, the first Russian drug-eluting stent "CALYPSO".

AIM OF STUDY To study immediate and medium-term results of Limus-eluting stents procedure in patients with acute coronary syndrome.

MATERIAL AND METHODS 304 patients with acute coronary syndrome were included into the research and were divided into 2 groups. The first group consisted of 156 patients with CALYPSO stent (Angioline, Russia). The other group consisted of 148 patients who had undergone revascularization with the XIENCE stent (Abbot Vascular, USA). Their health state was monitored via phone 3, 6, 9 and 12 months later. After the discharge from the hospital, the drug therapy was prescribed, and instrumental procedures of diagnostics were planned for the period of 9–12 months.

According to the results of the examination, patients with suspected or confirmed myocardial ischemia underwent follow-up coronary angiography.

RESULTS The success of implantation was 98.63% in the first group, and 99.4% in the second group. One fatal outcome occurred in both groups during hospitalization (thus making 0.64% и 0.67%). The placement of the CALYPSO stent in distal parts of coronary arteries requested significantly less time and contrast. Medium-term results of stenting in both groups appeared to be comparable (thus, all cause death 3 (1.92%) and 2 (1.35%), restenosis >50% 3 (1.92%) and 3 (2 %), late thrombosis — 0 in both groups, cardiac death — 0 in both groups. End points (MACE) in both groups were 1.28% and 0.67%.

CONCLUSION Taking into consideration immediate and medium-term results it can be concluded that domestic stents (CALYPSO) are comparable to stents XIENCE. The CALYPSO stent is more advantageous than the XIENCE in the delivery to the lesion focus while performing the procedure in distal flow.

Keywords: coronary stents, Russian stents, drug eluting stents, Calypso

For citation Chernyayev M.V., Faybushevich A.G., Muzganova Y.S. Endovascular treatment with limus eluting stents in patients with acute coronary syndrome. *Russian Sklifosovsky Journal of Emergency Medical Care.* 2019; 8(1): 45–52. DOI: 10.23934/2223-9022-2019-8-1-45-52 (In Russian)

Conflict of interest Authors declare lack of the conflicts of interests

Acknowledgments The study had no sponsorship

Affiliations

Mikhail V. Chernyayev	Physician for X-ray Endovascular Methods of Diagnosis and Treatment, postgraduate student of the Department of Advanced Surgery with a Course of Pediatric Surgery, PFUR, ORCID: 0000-0003-4925-7475.
Aleksandr G. Faybushevich	Cand. Med. Sci., Docent, Head of the Department of Department of Advanced Surgery with a Course of Pediatric Surgery, PFUR, ORCID: 0000-0001-7998-3051.
Yustina S. Muzganova	Resident of the Department of Department of Advanced Surgery with a Course of Pediatric Surgery, PFUR

ACS — acute coronary syndrom
AMI — acute myocardial infarction
CA — circumflex artery
CABG — coronary artery bypass grafting
CAD — coronary artery disease
CHF — chronic heart failure
CI — confidence interval
CVD — cardiovascular diseases
ECG — electrocardiography
EchoCG — echocardiography
FC — functional class
LADA — left anterior descending artery
LCA — left coronary artery
LV — left ventricle
MACE — major adverse cardiac events
NSTEMI — myocardial infarction without ST-segment elevation
PCI — percutaneous coronary intervention
RCA — right coronary artery
STEMI — myocardial infarction with ST-segment elevation
SYNTAX — Synergy Between Percutaneous Coronary Intervention with Taxus
TIMI — thrombolysis in myocardial infarction
TLR — target lesion restenosis

INTRODUCTION

Acute coronary syndrome (ACS) remains the leading cause of death and disability in the Russian Federation. While in the majority of Western countries there has been a significant decrease in mortality from cardiovascular diseases (CVD) recently, the CVD mortality remains high in the Russian Federation and it is about 3 times higher than in Europe [1]. Moreover, ACS often becomes the clinical debut of coronary artery disease (CAD) [2]. From the position of modern knowledge, the "golden standard" of treating patients with ACS is the combined use of endovascular surgery and modern pharmacological support both in the preoperative period and during percutaneous coronary intervention (PCI) [3].

From the results of large randomized studies, it follows that drug eluting stents are preferable to bare metal stents due to the lower incidence of complications in the mid-term and long-term periods. However, the introduction of drug eluting stents into daily practice did not solve a number of clinical and technical problems, including a considerable number of late thrombosis with stents of many models, the need to manage restenosis in the mid-term period and nonperfect delivery systems to the target site [4-6].

There are some mandatory requirements to modern models of stents. These are biocompatibility, the ability to be contrasted in X-ray, to be delivered and some others. The provision of these parameters is possible by improving the design features and the structure and type of polymer. The most common group of drugs used in the production of stents are "limuses" (sirolimus, everolimus, zotarolimus, biolimus, etc.)

The first Russian coronary stent coated with a bioresorbable sirolimus was Calypso, which is a modern representative of the latest generation of stents. At the same time, one of the most used and studied drug eluting stents in the world are Xience stents (everolimus) [7, 8].

In this study we report the experience of observing patients with ACS who were treated with Calypso stents (Angioline, Russia) and Xience stents *(*Abbott Vascular, USA) in two parallel groups for a period of up to one year.

The purpose of this study was to evaluate immediate and mid-term results from the use of Limus-eluting stents in ACS.

MATERIAL AND METHODS

The study included 304 patients who underwent endovascular myocardial revascularization for ACS from September 2015 to December 2016. This is a prospective multicenter study in the framework of cooperation of the Department of Advanced Surgery with the Course of Pediatric Surgery PFUR with specialized medical institutions.

Criteria for inclusion into the study:

- age from 35 to 85 years;
- unstable angina;
- acute myocardial infarction (AMI) with *ST* segment elevation;
- MI without *ST* segment elevation;
- *Syntax* score in a multi-vascular lesion less than 32 (more than 32, provided the patient refuses to undergo coronary artery bypass surgery).

Exclusion criteria:

- cancer, which therapy involves chemotherapy within six months after stent installation;
- chronic heart failure (CHF) stage III;
- the patient's refusal to adhere to dual antiplatelet therapy for any reason;
- a previously implanted stent in the symptom-responsible artery;
- an early understanding of the inability and/or the patient's desire to attend the control coronary angiography at the required time, as well as contact via telephone.

The groups were assembled consecutively, the number of included patients was limited by the stated temporary boundaries. All patients were divided into 2 groups. The model of a stent was the criterion for distribution into groups.

Group 1 included 156 patients with a Calypso sirolimus-eluting stent (Angioline, Russia).

Group 2 included 148 patients with everolimus-eluting Xience stent (Abbott Vascular, USA).

Upon admission to the hospital, patients who had not previously received acetylsalicylic acid, took a loading dose of at least 325 mg. Those who at the time of hospitalization did not take ticagrelor or clopidogrel constantly (at least 5 days) were prescribed preoperatively 180 mg of ticagrelor or 600 mg of clopidogrel in accordance with European recommendations for myocardial revascularization from 2014. Intraoperatively, unfractionated heparin in a dose of 70-100 U per body weight was administered in each patient. Activated clotting time was maintained at more than 250 sec.

Each patient underwent electrocardiography (ECG) and echocardiography (EchoCG), a standard set of laboratory studies, and also troponin T test (with a negative result on admission, repeated samples were performed 6 hours later).

All patients underwent coronary angiography to identify a symptom-responsible artery, which, in turn, was revascularized with a stent. After discharge from the hospital, patients received drug therapy, and instrumental diagnostic methods were planned for the period of 9–12 months. Patients with diagnosed or suspected myocardial ischemia were offered hospitalization for control coronary angiography. Patients with negative results of provocative tests continued to receive drug therapy.

To achieve the goal set in the study, we carried out a survey of a number of parameters characterizing patients in both groups, as well as the technical side of the procedures performed. So, we assessed the incidence of late/acute thrombosis, repeated revascularization in the target vessel due to clinically significant restenosis, the number of deaths due to cardiac reasons, *MACE* parameter *(major adverse cardiac events)*, defined as the total number of clinical coronary events, including coronary death, myocardial infarction and re-targeted revascularization, the dynamics of the class of angina (or the patient's clinical status), possible complications from taking the prescribed drugs and some others, the frequency of the patient's treatment to the doctor for any reason. We evaluated aspects of the procedures such as the incidence of intraoperative complications (arterial dissection, *no-reflow* syndrome, lateral branch occlusion, incomplete expansion of the stent, etc.), time taken to perform the intervention, features of the delivery of stents under different morphological conditions and some others.

CHARACTERISTICS OF PATIENTS INCLUDED INTO STUDY

When comparing the main clinical and anamnestic data, patients of Group 1 and Group 2 did not statistically significantly differ from each other in clinical, demographic indicators, as well as risk factors. The Table 1 shows a comparison of the main characteristics of patients included into the study.

In both groups, the majority of patients were represented by male patients: 104 (66.7%) and 98 (66.2%), respectively. The average age of patients was 70±11.2 years in the 1st group and 68±4.6 years in the 2nd group (p>0.05). Most patients of Group 1 and Group 2 were admitted to the hospital with unstable angina: 81 (51.9%) and 72 (48.6%), respectively (p>0.05). A lot of patients, more than a third in both groups, were taken to a medical institution with STEMI: 55 (35.3%) and 58 (39.2%), respectively. Some patients had AMI in history. This figure was 8.2% in the 1st group, and 7.4% in the 2nd group. Four patients of the 1st group (2.6%) and 3 patients of the 2nd group (2%) experienced ischemic stroke. Of the total number of patients in the 1st group, 31 (19.9%) suffered from diabetes. In the 2nd group, the number of patients with this pathology was 25 (16.9%).

On the 1st day after admission, all patients of the 1st and 2nd groups underwent EchoCG study and determination of the ejection fraction (according to Simpson). In the 1st group this indicator was 49.5±3.6%, and in the 2nd group it was 50.4±3.9%.

Patients of the 1st group were delivered to the hospital on average 115±55 minutes after the onset of clinical symptoms. For patients of the 2nd group, this indicator was 110±45 min. In patients with STEMI, we measured the average time from the moment of arrival to the hospital to the balloon inflation in the occluded artery (door-to-balloon time). For both patients of Group 1 and Group 2, this value was 40±5 min.

When evaluating angiographic data we learnt that patients of both groups had one-, two- and three-vessel disease. Two-vessel lesions were observed most frequently in 66 (43.6%) patients of the 1st group and in 69 (46.6%) patients of the 2nd group.

The most unfavorable three-vascular lesion was observed in 27 (17.1%) patients of the 1st group and 18 (12.2%) of the 2nd group. In both groups we had to deal with a lesion of the left coronary artery (LCA): 16 (5.8%) patients of the 1st group and 12 (4.7%) patients of the 2nd group.

Calcification of the coronary arteries occurred in approximately one third of all patients: 83 (30.1%) cases in the 1st group and 81 (35.5%) cases in the 2nd group. High angulation occurred in 21 patients (7.6%) in the 1st group and in 13 (5.1%) of the 2nd group. The bifurcation lesion was revealed in 27 patients (9.8%) of the 1st group and 25 (9.9%) patients of the 2nd group.

A total of 292 Calypso stents were implanted in patients in the 1st group. In Group 2 patients, 265 stents were implanted. Accordingly, the average number of stents per patient in the 1st and 2nd group was 1.9 and 1.8. The average length of the stented segment was 26.3±13.1 mm in the 1st group, and 24.8±6.7 in the 2nd group. The mean diameter of implanted stents in the 1st and 2nd group was 2.92±0.5 and 3.1±0.39, respectively.

Table 1

Clinical and angiographic characteristics of patients in both groups

Parameter	Group 1, n=156	Group 2, n=148	Significance of differences
Male	104 (66.7%)	98 (66.2%)	p>0.05
Female	52 (33.4%)	50 (33.8%)	p>0.05
Mean age	70±11.2	68±4.6	p>0.05
Unstable angina	81 (51.9%)	72 (48.6%)	p>0.05
STEMI	20 (12.8%)	18 (12.2%)	p>0.05
NSTEMI	55 (35.3%)	58 (39.2%)	p>0.05
Smoking	84 (53.8%)	80 (54.1%)	p>0.05
Myocardial infarction in history	13 (8,2%)	11 (7.4%)	p>0.05
Arterial hypertension	150 (96.1%)	141 (95.3%)	p>0.05
Hypercholesteremia	84 (53.8%)	76 (51.4%)	p>0.05
Obesity	26 (16.6%)	25 (16.9%)	p>0.05
Diabetes mellitus	31 (19.9%)	25 (16.9%)	p>0.05
Stents in history	10 (6.4%)	9 (6.1%)	p>0.05
Stroke in history	4 (2.6%)	3 (2%)	p>0.05
Ejection fraction, %	49.5±3.6	50.4±3.9	p>0.05
One-vessel-lesion	63 (39.3%)	61 (41.2%)	p>0.05
Two-vessel lesion	66 (43.6%)	69 (46.6%)	p>0.05
Three-vessel-lesion	27 (17.1%)	18 (12.2%)	p>0.05
Lesion of LCA stem	16 (5.8%)	12 (4.7%)	p>0.05
Calcinosis	83 (30.1%)	81 (35.5%)	p>0.05
Angulation more than 45	21 (7.6%)	13 (5.1%)	p>0.05
Time gap (minutes) between manifestation of symptoms and hospitalization	115±55	110±45	p>0.05
Door-to-baloon time (min)	40±5	40±5	p>0.05
Average size of stents (mm)	2.92±0.5	3.1±0.39	p>0.05
Totally installed	292	265	p>0.05
Mean number of stents for 1 patient	1.9	1.8	p>0.05
SYNTAX score	21±6.2	19±4.9	p>0.05

Notes: LCA — left coronary artery; STEMI — myocardial infarction with ST-segment elevation; NSTEMI — myocardial infarction without ST-segment elevation; SYNTAX — Synergy Between Percutaneous Coronary Intervention with Taxus

IMMEDIATE RESULTS OF STENT INSTALLATION IN BOTH GROUPS

We calculated the time spent on the intervention in patients of both groups from the moment of their delivery to the operating room until the transfer to the intensive care unit. The total duration of stay in the X-ray operating room in the 1st group was 63.4±20.8 minutes. In the 2nd group, the total duration of assistance was 64.6±21.2 min. Given the average number of implanted stents per patient, the median time per 1 stent in the 1st group was 33.4 (95% CI 22.4–44.3) min, and 35.9 (95% CI 24.1–47.6) min in the 2nd group. Next, we calculated the time spent on implantation in

different segments of the coronary arteries without taking into account actions not directly related to manipulation of the stent-system. We did not include the time for laying the patient on a table and removing him/her from the table, forming access, performing coronary angiography, setting up a guide and primary angioplasty. We assessed time spent on such technical actions as stent to the target lesion, additional predilation, if delivery fails the first time, the use additional techniques to hold the endoprosthesis to the desired location (rail tecgnique, anchor technology, etc.) and post-dilatation.

A common trend in both groups was an increase in the duration of stent implantation from proximal to distal segments. When installing stents in the proximal third of the left anterior descending artery (LADA), the circumflex artery (CA) and the right coronary artery (RCA) (respectively 3.9 ± 0.8 and 3.8±0.9 min, 4.0±0.9 and 3.9±0.6 min, 3.9±0.6 and 3.8±0.7 min), as well as in the middle third of the LADA, CA and RCA (4.4±0.8 and 4.6±0.7 min, 4.6±0.7 and 4.6±0.8 min, 4.2±0.5, and 4.1±0.4 min) there were no statistically significant differences (p>0.05). However, when comparing the time spent on implantation in the distal segments (5.2±1.1 and 6.4±0.9 min, 5.3±1.0 and 6.4±0.7 min, 5.8±0.9 and 6.8±0.7 min), the procedure in the 2nd group was significantly longer (p<0.05). Thus, the use of the Calypso stent for interventions on the distal coronary artery segments in our study required a statistically significantly less time. This might have been associated with its greater deliverability in complex morphological lesions due to some of its design features.

A set of certain technical actions during the stenting procedure, as a rule, is accompanied by the consumption of a contrast agent. We analyzed the average consumption of contrast during the stenting procedure in the general and different segments of the coronary flow. When assessing the total flow of the contrast agent per patient in each group (from the moment of puncture to the final control survey), it turned out that this indicator averaged 185±30 ml in the 1st group, and 200±35 ml in the 2nd group. The increase in the consumption of a contrast agent during interventions from proximal to distal segments was regular in both groups. When installing vascular stents in the proximal third of LADA, CA, RCA (40±10 and 50±15 ml, 45±15 and 50±15 ml, 40±10 and 45±10 ml), as well as in the middle third of LADA, CA, RCA (respectively 55±20 and 60±15 ml, 60±15 and 65±15 ml, 60±15 and 60±10 ml), there were no statistically significant differences (p>0.05). However, when comparing the amount of contrast consumed in implantation in the distal segments (65±15 and 85±10 ml, 65±10 and 80±5 ml, 65±10 and 80±10 ml), a statistically significantly more substance was needed in the 2nd group (p <0.05). Thus, the use of the Calypso stent for interventions on the distal coronary artery segments in our study required a statistically significantly lower amount of contrast, which may be associated with the shorter intervention duration in the 1st group.

When evaluating immediate results of stenting, it turned out that the success of implantation was 98.63% in patients of the 1st group with Calypso stents. This indicator was 99.4% in patients of the 2nd group with Xience stents. The implantation was successful if there were the adequate expansion of the stent with a residual stenosis of less than 10%, as well as *TIMI III* blood flow. In case of dissection, the implantation was successful if it was possible to perform defect optimization using angioplasty or implanting an additional stent. The Table 2 shows the main immediate results of the procedures in patients of both groups.

Table 2

Immediate results of stent installation

Comparable aspects of the procedure	Group I n=292	Group II n=265	Significance of differences
Optimal implantation of a stent	288 (98.63%)	262 (98.9%)	p>0.05
Post-dilatation	252 (86.3%)	222 (83.8%)	p>0.05
Technical specifics			
Mean pressure of implantation	16±4 atm.	16±4 atm.	p>0.05
Incomplete expansion of a stent	2 (0.68%)	1 (0.37%)	p>0.05
Dislocation of a stent on a baloon	0	0	p>0.05
Complications			
Aortal dissection	2 (0.68%)	2 (0.74%)	p>0.05
Occlusion of lateral branches	2 (0.68%)	0	p>0.05
No-reflow syndrome	0	0	p>0.05

Incomplete expansion of the Calypso stent occurred twice of the total number of implanted stents (0.68%). The similar situation was observed in the 2nd group once (0.42%). In all situations, this occurred during the implantation of vascular stents into the zone of rigid plaque. We tried to optimize the expansion of the stent using post-dilatation of high-pressure cylinders, including larger diameter, but this wasn't successful. Anyway, in most cases, namely in 86.3% of implantations in the 1st group, post-dilatation was performed. Post-dilatation was also performed in 83.9% of cases after Xience stent installation.

We had no cases of stent displacement from the delivery system in both groups.

In 2 clinical situations in the 1st group, as well as in 2 cases in the 2nd group, regional dissection took place after stent implantation. In our opinion, these complications were caused by the use of overpressure during post-dilatation and the incorrect position of the balloon relative to the stent borders. In one case in each group, this required the use of an additional stent, in other cases an additional long-term (more than 60 s) angioplasty was performed in order to optimize the defect. Anyway, the occurrence of dissection could not lead to fatal complications.

In 2 cases (0.68%) after implantation of the Calypso stent, an occlusion of the lateral branch was revealed. Both times, this was the case with stent implantation in the middle third of the LADA, diagonal arteries were occluded. Attempts were made to restore the lumen of the closed arteries, but it was not successful. The structure of the Calypso stent has a combined cell, namely, open in the body of the stent and closed at the end sections. In both cases, the ostia of the occluded diagonal arteries were covered with marginal stent segments having a closed cell, which did not allow for performing bifurcation techniques. Later we began to take into account this design feature, and such complications did not repeat.

We did not observe *no-reflow* syndrome in both groups.

At the hospital stage, due to the development and progression of acute cardiovascular insufficiency, 1 death occurred in each group (0.64% and 0.67%, respectively). We do not associate this with the features of the procedure and the characteristics of a particular stent model.

The average period of hospitalization in the 1st group was 8.1±2.4 days, and 7.9±2.6 days in the 2nd group.

When evaluating instrumental and laboratory research methods, a positive trend was observed towards the end of the hospital stay. The average value of the Simpson ejection fraction in the 1st group upon admission to the hospital was 49.5±3.6%. On the 5th day of hospitalization, this indicator was 53.2±3.9%. We performed the control echocardiography no earlier than on day 5, as we tried to avoid a false result due to a possible compensatory increase in the ejection fraction within first few days after the acute coronary events. The average value of the Simpson ejection fraction in the 2nd group when admitted to hospital was 50.4±3.9%. On the 5th day of hospital stay, this indicator changed to 54±3.2%.

The oxygen saturation indicator in the blood upon admission was 93±2% in the 1st group. This indicator changed to 98±1% on the 5th day of hospital stay. The measurements were carried out in the patient's calm state without prior exercise. The oxygen saturation indicator in the blood upon admission was 93±3% in the 2nd group. This indicator changed to 99±1% on the 5th day of hospital stay.

One patient of the 2nd group underwent CABG due to the severity of damage to the entire coronary system, the need for multiple revascularization and the high risk of endovascular intervention.

When performing a control ECG, no signs of acute damage were observed in any patient. Recurrent myocardial infarction didn't take place during the hospitalization period in both groups.

Acute thrombosis of implanted stents (0–24 hours) did not occur in any patient. None of the patients needed repeated emergency PCI.

In control blood tests, the general trend was a slight increase in creatinine level, which we associated with the load of the kidneys with radiopaque substances. There was also a decrease in absolute indices of leukocyte formula, which might indicate a decrease in the manifestation of inflammatory reactions.

When operating a symptom-responsive artery, patients reported an improvement in clinical status even during their stay on the operating table. After the intervention and prescribing antianginal therapy patients did not notice angina at the hospital.

MID-TERM RESULTS OF STENTING IN BOTH GROUPS

The telephone or personal communication was available in 152 patients of the 1st group (97.43%) and 145 patients (97.97%) of the 2nd group. We had the opportunity to receive information about the clinical condition of the observed, as well as to collect some additional information. The Table 3 shows the main average results of the procedures and the clinical status of patients in both groups.

Table 3

Medium-term results of stent installation in both groups and clinical state of patients during observation

Parameter	Group 1	Group 2	Significance of differences
Total number of patients in the beginning of the study	156	148	-
Patients observed during the entire period of the study	152(97.43%)	145 (97.97%)	p>0.05
Good clinical result	129 (84.87%)	114 (78.62%)	p<0.05
Recurrent angina which includes: - FC III - FC II	23(15.13%) 18 (78.3%) 5 (21.7%)	31 (21.38%) 24 (77.4%) 7 (22.6%)	p>0.05
Coronary bypass surgery	1 (0.64%)	0	p>0.05
Restenosis >50%	3 (1.92%)	3 (2 %)	p>0.05
Clinical restenosis - TLR	1 (0.64%)	0	p>0.05
Major adverse cardiac events	1.28 %	0.67%	p>0.05

Dual antiplatelet therapy was prescribed for 12 months. In both study groups, all 100% of patients took aspirin for at least 6 months. However, the results of a telephone survey revealed that for one reason or another 28 (18%) patients in the 1st group and 20 (13.5%) people in the 2nd group had discontinued taking aspirin from 7 to 12 months. There was the similar situation with ticagrelor and clopidogrel. All patients took these drugs for at least 6 months. In the period from 7 to 12 months, 16 (10.3%) people in the 1st group and 15 (10.1%) in the 2nd group discontinued taking the drugs.

In the vast majority of cases, patients of both groups took clopidogrel: 130 (83.3%) and 131 (88.5%) people in the 1st and 2nd group, respectively. Ticagrelor was taken respectively by 26 (16.7%) and 17 (11.5%) patients in the 1st and 2nd study group. Patients didn't change the drug. Patients of both groups had no complications in the mid-term period associated with receiving dual antiplatelet therapy.

According to the telephone questionnaire, the clinical result of stenting was also evaluated. The good clinical result was the absence of angina after revascularization or clinical compensation as a result of taking the optimal drug therapy.

Thus, 129 respondents of the 1st group (84.87%) had a good clinical result for at least 12 months after the procedure. In 23 patients (15.13%) of the 1st group, angina pectoris returned. Patients noted that anginal pain (15 patients) or severe dyspnea (8) occurred after exercise and eliminated independently or after taking nitroglycerin.

In similar periods of observation (12 months), a good clinical result was revealed in 114 patients (78.62%) of the 2nd group. However, in 31 patients (21.38%) angina returned. Patients noted that anginal pains (in 20 patients of the 2nd group) or severe dyspnea (in 11 patients of the 2nd group), as well as in the 1st group, occurred after exercise and eliminated independently or after taking nitroglycerin.

When assessing the average results in the subgroup of patients with diabetes, it turned out that a good clinical result was achieved in 23 patients in the 1st group (74.2% of the total number of the subgroup) and in 19 patients in the 2nd group (76% of total number of subgroups). At the same time, angina of III functional class (FC) was determined in 6 cases, and FC II in two cases of the 1st group. In the 2nd group, angina FC III was revealed in 5 patients, and FC II in one patient.

For verification of angina pectoris, patients were referred for consultation to a cardiologist. According to the consultation, 18 (78.3%) patients of 23 of the 1st group had angina pectoris FC III, and 5 (21.7%) patients had angina pectoris FC II. In the 2nd group, 24 (77.4%) patients had angina pectoris FC III, and 7 (22.6%) patients had angina pectoris FC II. This indicator wasn't statistically significantly different in two groups (p>0.05).

All patients from both groups of patients with angina pectoris were hospitalized with subsequent coronary angiography.

When conducting Echo-CG in the mid-term observation period, it turned out that the average value of the Simpson ejection fraction in the 1st group was 57.6±2.8%. In the 2nd group, the value of the ejection fraction at the same time of observation was 56.5±3.6%.

In both groups, there was a clear positive trend (p<0.05, statistically significant) increase in the ejection fraction compared with the hospitalization period. We primarily associate this improvement with adequate drug therapy. At the same time, a comparative analysis of the ejection fraction between patients of the 1st and 2nd group during similar periods of observation demonstrated the absence of statistically significant differences (p>0.05).

Before the discharge and in the med-term period, we conducted a test with a 6-minute walk. In patients of the 1st group, before discharge from the hospital, the average result was 405±55 m, and in the 2nd group, this indicator was 395±65 m. In the mid-term period, in patients in the 1st group, the result of this test was 450±165 m, and 440±130 m in

the 2nd group. The increase in the mean distance covered in patients of both groups draws attention. However, an increase in the error indicates a normal functional state of a number of patients on the one hand, and recurrent angina in a certain number of patients on the other hand, and, as a result, a decrease in their FC.

Cycle ergometer test was also performed in both groups of patients. The results showed that in addition to 23 patients of the 1st group, who had recurrent angina, another 70 patients had a positive test. In the 2nd group, the test was positive in 31 patients with recurrent angina pectoris and in 58 more patients.

All patients with recurrent angina/or positive cycle ergometer test, 93 (59.6%) and 89 (60.1%) patients of the 1st and 2nd group, respectively, were hospitalized again, subsequently they underwent control coronary angiography followed by a decision on the need for endovascular revascularization.

By 12 months of observation, in addition to one patient who died at the hospital stage, another 2 patients of the 1st group died. The total mortality rate was 1.92%. However, it became known from relatives of these patients that the cause of death was not associated with the pathology of the cardiovascular system in any patient.

One patient of the 1st group underwent CABG in the period of repeated hospitalization due to recurrent angina pectoris.

We noted that the vast majority of patients in both groups did not have any complaints during the control examination, stents satisfactorily performed their function. However, during control coronary angiography in 3 patients (1.92%) of the 1st group, restenosis of more than 50% was noted. In each of these events, diffuse restenosis was noted. However, in one patient of the 1st group, restenosis exceeded 80%. This episode was qualified as a clinically significant restenosis and required targeted revascularization. When conducting a control study in 3 patients (2%) of the 2nd group, restenosis of more than 50% was also noted. In each case, diffuse restenosis was noted. There were 2 patients with diabetes,one in each group, of the total number of patients in both groups with 50% restenosis.

Achieving a composite endpoint, defined as the total number of clinical coronary events at the time of observation *(MACE - Main Acute Coronary Event)*, including cardiac death, recurrent myocardial infarction and clinical restenosis (*TLR)*, was 1.28% and 0.67%, respectively.

The mid-term results of stenting in both groups were comparable and did not statistically significantly differ from each other (in the 1st and 2nd group, respectively, death from all causes 3 (1.92%) and 2 (1.35%) (p>0.05), restenosis more than 50% 3 (1.92%) and 3 (2%) (p>0.05). The absence of late thrombosis in both groups was extremely important. There were no cases of cardiac death.

FINDINGS

1. The use of Calypso stent while observing generally accepted recommendations for the implementation of endovascular interventions is successful in the vast majority of cases.
2. The immediate and mid-term angiographic results of endovascular interventions in patients with acute coronary syndrome with the use of the Calypso stent are comparable to those with Xience stents.
3. The Calypso stent has no less clinical efficacy and safety compared to Xience Prime stent.
4. The Calypso stent has an advantage over the Xience stent in the aspect of delivery to the target lesion when installing a stent in the distal parts on the background of a complex morphological lesion.

REFERENCES

1. Shakhnovich R.M. Rivaroxaban in patients with acute coronary syndrome. *Neotlozhnaya kardiologiya*. 2016; (3): 3–16. (In Russian).
2. Oganov R.G., Fomina I.G., eds. *Heart disease*. Moscow: Litterra Publ., 2006. 1328p. (In Russian).
3. Shugushev Z.Kh., Maksimkin D.A., Petrov A.S., et al. Acute coronary syndrom: last and future. *Zemskiy vrach*. 2014; 1 (22): 31–36. (In Russian).
4. Hermiller J.B., Raizner A., Cannon L., et al. Outcomes with the polymer-based paclitaxel-eluting TAXUS stent in patients with diabetes mellitus: the TAXUS-IV trial. *J Am Coll Cardiol*. 2005; 45(8): 1172–1179. PMID: 15837245. DOI: 10.1016/j.jacc.2004.10.075.
5. Van de Werf F, Bax J, Betriu A, et al. Management of acute myocardial infarction in patients presenting with persistent ST-segment elevation: the task force on the management of ST-segment elevation acute myocardial infarction of the European Society of Cardiology. *Eur Heart J*. 2008; 29: 2909–2945. PMID: 19004841. DOI: 10.1093/eurheartj/ehn416.
6. Moses J.W., Leon M.B., Popma J.J., et al. Sirolimus-eluting stents versus standard stents in patients with stenosis in a native coronary artery. *N Engl J Med*. 2003; 349(14): 1315–1323. PMID: 14523139. DOI:10.1056/NEJMoa035071.
7. Kudryashov A.N., Lopotovskiy P.Yu. Comparative estimation of mechanical properties of coronary stent “Sinus”. *Diagnosticheskaya i interventsionnaya radiologiya*. 2014; 8(1):70–77. (In Russian).
8. Chernyayev M.V., Koledinskiy A.G., Faybushevich A.G., Topchyan I.S. Coronary stents: past, present, future. Domestic elaborations in endovascular surgery (literature review). *Diagnosticheskaya i interventsionnaya radiologiya.* 2016; 10(4); 51–56. (In Russian).

Received on 24.09.2018

Accepted on 07.10.2018