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The Incidence and Possible Predictors of Coronary Restenosis

Objective — Assess time and possible predictors of restenosis after the implantation of first- and second-generation coronary stents and bare metal stents (BMSs) in patients with stable coronary artery disease after elective coronary stenting.

Materials and Methods — From 2010 to 2014, 3,732 (2,897 males, 60 [53; 68] years old) patients with stable exertional angina of functional class I–III underwent coronary stenting. From 2014 to 2017, 1,487 (1,173 males and 314 females) patients returned. Repeat coronary angiography was performed in 699 patients.

Results — A total of 644 first-generation stents, 5,321 second-generation stents, and 473 BMSs were implanted. During the control coronary angiography, contrasting was repeated for 193 first-generation stents, 899 second-generation stents, and 77 BMSs. Restenosis (stenosis of 50% or more in the previously stented segment) was detected in 28 (14% of angiographic control) first-generation drug-eluting stents, 94 (10%) second-generation drug-eluting stents, and 21 (27%) BMSs. Patients with BMS restenosis returned significantly earlier than patients with restenosis of the first- and second-generation drug-eluting stents (11 [6, 27] months vs. 32 [11; 48]) months and 24 [12; 42] months, respectively; $p<0.05$). The initial and repeat levels of high-sensitivity C-reactive protein (hs-CRP) were higher in patients with restenosis (2.2 [1.2, 5.0] mg/L vs. 2.1 [1.0, 4.6] mg/L, respectively; $p> 0.05$) than in patients without restenosis (2.0 [0.9, 4.2] mg/L vs. 1.9 [0.7, 3.5] mg/L respectively, $p>0.05$). Blood levels of hs-CRP ≥2 mg/L according to receiver operating characteristic curve (ROC) analysis at return visit were used as a predictor to identify restenosis of stents with a diameter <3 mm and a length >25 mm – area under the curve (AUC) 0.67 (95% confidence interval (CI) 0.51–0.84), $p <0.05$, odds ratio 3.7 (95% CI 1.1–12.1), $p<0.05$. Stent type had a significant effect on the time to restenosis in the survival analysis ($p<0.0005$).

Conclusion — The time from coronary stenting to the return visit of patients presenting with restenosis after the implantation of first- and second-generation drug-eluting stents is consistent; median time of the return visit of patients with restenosis of the first-generation stents was 2–3 years after coronary stenting. Blood levels of hs-CRP ≥2 mg/L at the return visit is a predictor of restenosis of stents with a diameter <3 mm and a length >25 mm.

Keywords — Coronary stenting; atherosclerosis; restenosis; high-sensitivity C-reactive protein

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The introduction of coronary stents into clinical practice was revolutionary in the treatment of patients with coronary artery disease (CAD) and significantly improved their quality of life. However, arterial wall damage due to the intervention and subsequent proliferation of neointima led to early restenosis of the stented artery. Bare metal stents (BMSs) were developed to counter perioperative occlusions of coronary arteries caused by dissection of the vessel at the intervention site for balloon angioplasty [1].

Implantation of a BMS, which consists of a metal mesh frame, was associated with increased thrombogenicity and probability of restenosis of the previously stented segment. Drug elution from the stent coating suppresses the excessive proliferation of neointima and reduces the likelihood of restenosis when compared with non-drug-eluting (bare metal) stents [2–4]. Unlike BMSs, first-generation stents with an antiproliferative coating reduced the probability of revascularization of the target vessel and target lesion, as well as the incidence of severe cardiovascular complications [5, 6]. However, first-

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generation stents posed a risk of very late thrombosis of the stent. Second-generation stents have a better safety and efficacy profile than first-generation stents due to optimized structure of the stent struts, improved biocompatible coating, and reduced doses of anti-proliferative agents [7].

The rate of restenosis varies significantly in different studies depending on population, terms, and methods of control. The earliest publications on the relative rate of restenosis in first- and second-generation stents identified no difference between the stent generations. Later studies, with a larger number of patients and longer follow-up periods, tended to identify a lower rate of restenosis with second-generation stents. Currently, first-generation stents are not used, but a significant number of patients who underwent coronary stenting with BMSs and first-generation stents require continued prognosis studies. In 2018, the European Society of Cardiology [8] recommended against the use of BMSs in all categories of patients. In Russia, the implantation of bare metal stents presented 42.4% of all stenting procedures in 2018 [9].

The objective of this study was to assess time and possible predictors of restenosis after the implantation of first- and second-generation coronary stents and BMSs in patients with stable CAD. The study was carried out in a major federal clinical center with a large number of interventions performed annually.

Materials and methods

This study included 3,732 patients (2,897 males and 835 females, age 60 [53; 68] years old), with documented CAD (stable angina functional class I–III) who underwent coronary stenting (implantation of paclitaxel, siro-/evero-/zotarolimus-eluting stents) in the Russian National Cardiology Research Center, in 2010–2014.

The study excluded patients with acute myocardial infarction, acute cerebrovascular accident, surgical or endovascular interventions within the previous six months, cancer, severe renal or hepatic insufficiency, inflammatory diseases, decompensated diabetes, and patients taking immunotropic drugs. Acetylsalicylic acid 75–100 mg/day, clopidogrel 75 mg/day, statins depending on the levels of total cholesterol (TC) and low-density lipoprotein (LDL) following the current recommendations, beta-blockers, angiotensin-converting enzyme (ACE) inhibitors or sartans, nitrates, if indicated, were administered to each patient in the perioperative period and subsequently.

The study was performed under the principles of the Declaration of Helsinki. The study protocol was approved by the Ethics Committee of the Russian National Cardiology Research Center.

All patients underwent standard clinical and instrumental examination, including medical history, physical examination, clinical and biochemical blood tests, electrocardiography, echocardiography, exercise stress tests for assessing myocardial ischemia, and coronary angiography. The last was carried out with contrast enhancement via radial access, in at least four projections for the left coronary artery, and at least two orthogonal projections for the right coronary artery (RCA). Restenosis was defined as 50% or greater narrowing of the stented region, a progression of coronary atherosclerosis, more than 50% in a previously intact region in case of new stenosis, or increasing severity of the existing >30% stenosis by 20% or more. Blood levels of high-sensitivity C-reactive protein (hs-CRP) were detected by a latex-enhanced immunoturbidimetric assay using ARCHITECT c8000. All measurements were made at inclusion in the study before the endovascular intervention.

From 2014 to 2017, 1,487 (1,173 males and 314 females) patients returned. The reasons for repeat visits were recurrent exertional angina or other presentations of myocardial ischemia. The study did not confirm myocardial ischemia in 788 patients, and repeat coronary angiography was not performed. Repeat coronary angiography was performed in 699 patients.

Statistical analysis. Data are presented as median [25th percentile; 75th percentile] as they do not comply with the parameters of a normal distribution. Angiographic characteristics are presented as mean ± standard deviation (Table 1). Multiple intergroup comparisons were evaluated using the Kruskal-Wallis test. Comparison of the groups by qualitative attributes (sex, prevalence of hypertension, diabetes mellitus) used the two-tailed Fisher's exact test and chi-squared test. Survival was evaluated by the Kaplan-Meier method.

The statistical processing in this study used Excel, IBM SPSS Statistics 20.0. (US) and Statistica 9.0. receiver operating characteristic curve (ROC) analysis was performed using PRISM software. Differences were considered to be statistically significant when $p<0.05$.

Results

The angiographic characteristics of patients are presented in Table 1.

Repeat coronary angiography was performed in 699 patients. During control coronary angiography, contrasting was repeated for 193 first-generation stents, 899 second-generation stents, and 77 BMSs. Restenosis of the previously stented segments was identified in

Table 1. Angiographic characteristics of patients included in the study (n=3,732)

Parameter	Value
Number of affected main coronary arteries	
Single-vessel disease, abs. (%)	1,237 (33)
Two-vessel disease, abs. (%)	1,369 (37)
Left main coronary artery disease	204 (5)
Mean number of affected vessels per patient	2.0±0.89
Mean number of implanted stents per patient	1.7±0.94
Mean number of stents deployed in the affected artery	1.3±0.67
Mean diameter of implanted stents per patient, mm	3.11±0.54
Mean length of implanted stents per patient, mm	24.81±8.45
Types of stents implanted, abs. (%)	
First-generation stents	644 (10)
Second-generation stents	5321 (83)
BMSs	473 (7)

Data are presented as an absolute (abs.) number of patients (%) or M±σ. BMS, bare-metal stent.

28 first-generation stents (14% of angiographic control), 93 second-generation stents (10% of angiographic control), and 21 BMSs (27% of angiographic control). A total of 429 patients underwent repeat revascularization.

Table 2 provides the comparative clinical and laboratory characteristics of patients with different types of implanted stents. The main blood levels are given for the first and repeat visits.

The groups differed significantly by age and blood levels of total cholesterol and triglycerides at the first visit and by age and body mass index at the return visit. There were no differences between the patient groups in traditional risk factors, time to return visit after stenting, or other laboratory parameters.

Time to return visit of patients and laboratory values

Patients with BMS restenosis returned significantly earlier than patients with restenosis of first- and second-generation drug-eluting stents (11 [6, 27] months

Table 2. Comparative clinical and laboratory characteristics of patients with different types of implanted stents (n=699)

Parameter	Drug-eluting stents (n=629)	BMSs (n=42)	Drug-eluting stents + BMSs (n=28)	p
Age, years				
First visit	60 [54; 68]	58 [50; 63]	64 [56; 72]	<0.05
Return visit	63 [56; 70]	59 [51; 64]	66 [57; 75]	<0.05
BMI, kg/m²				
First visit	29 [26; 32]	32 [28; 36]	27 [23; 30]	>0.05
Eeturn visit	29 [27; 33]	33 [27; 35]	25 [24; 28]	<0.05
Hypertension, n (%)	532 (84)	37 (80)	27 (84)	>0.05
DM, abs. number (%)	116 (18)	10 (22)	3 (9)	>0.05
Time to return visit, months	20 [12; 37]	18 [9; 30]	19 [12; 36]	>0.05
Total cholesterol, mmol/L				
First visit	4.7 [4.0; 5.8]	5.8 [4.9; 6.5]	4.9 [3.9; 5.7]	<0.05
Return visit	4.4 [3.7; 5.1]	4.2 [3.5; 5.2]	4.8 [3.6; 6.2]	>0.05
Triglycerides, mmol/L				
First visit	1.6 [1.2; 2.2]	1.7 [1.1; 2.7]	1.1 [0.8; 1.8]	<0.05
Return visit	1.5 [1.1; 2.0]	1.4 [1.1; 2.1]	1.2 [0.9; 1.9]	>0.05
LDL, mmol/L				
First visit	2.8 [2.2; 3.8]	3.5 [2.5; 3.8]	2.9 [2.3; 3.6]	>0.05
Return visit	2.5 [2.0; 3.1]	2.3 [1.9; 3.1]	3.1 [2.3; 4.2]	>0.05
HDL, mmol/L				
First visit	1.0 [0.9; 1.2]	0.9 [0.8; 1.2]	1.1 [1.1; 1.3]	>0.05
Return visit	1.1 [0.9; 1.3]	0.9 [0.8; 1.3]	1.2 [1.1; 1.4]	>0.05
Hs-CRP, mg/L				
First visit	2.2 [1.1; 4.6]	3.3 [1.7; 7.3]	1.2 [0.6; 3.6]	>0.05
Return visit	1.5 [0.8; 3.4]	1.9 [0.7; 6.4]	1.6 [0.2; 2.0]	>0.05

Data are presented as median and interquartile range. The significance level of data comparisons of the three groups is given.
BMS, bare metal stent; BMI, body mass index; DM, diabetes mellitus; LDL, low-density lipoproteins; HDL, high-density lipoproteins; hs-CRP, high-sensitivity C-reactive protein.

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vs. 32 [11; 48]) months and 24 [12; 42] months, respectively; p<0.05). The hs-CRP levels at the return visit in patients with BMS were lower than in patients with restenosis of first- and second-generation stents (1.1 [0.6, 2.0] mg/L vs. 2.1 [1.0; 4,2] mg/L, p<0.05, and 2.9 [1.3, 5.2] mg/L, respectively). LDL levels at the return visit in patients with restenosis of second-generation stents were significantly lower than in patients with restenosis of first-generation stents (2.4 [2.0, 3.1] mmol/L vs. 3.3 [2,6; 4,3] mmol/L, respectively). Total cholesterol levels at the return visit in patients with restenosis of second-generation stents were reduced. At the return visit, 10% of patients diagnosed with restenosis had LDL blood concentrations of 1.8 mmol/L and lower. The groups of patients did not differ in other laboratory values or traditional risk factors.

The initial and repeat levels of hs-CRP were higher in patients with restenosis (2.2 [1.2, 5.0] mg/L vs. 2.1 [1.0, 4.6] mg/L, respectively; p>0.05) than in patients without restenosis (2.0 [0.9, 4.2] mg/L vs 1.9 [0.7, 3.5] mg/L respectively, p>0.05). Blood levels of hs-CRP ≥2 mg/L according to ROC analysis at the return visit were used as a predictor to identify restenosis of stents with a diameter <3 mm and a length >25 mm (area under the curve [AUC] 0.67 [95% confidence interval [CI] 0.51–0.84], p<0.05, odds ratio 3.7 [95% CI 1.1–12.1, p<0.05]) (Figure 1).

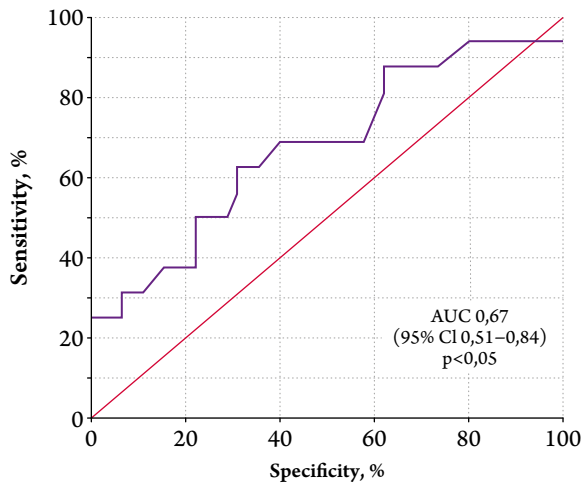
The median time to onset of restenosis was 60 months in patients with first-generation stents, 59 months in patients with second-generation stents, and 30 months in patients with BMSs (Figure 2). Stent type had a significant effect on the time to restenosis in the survival analysis (p<0.0005).

Discussion

Coronary stenting is one of the main treatment methods for patients with CAD. Stents are commonly used in clinical practice, and improvements are continuously made to their load-bearing structures and biocompatibility. The use of drug-eluting stents, unlike BMSs, made it possible to significantly reduce the incidence of in-stent restenosis by inhibiting acute inflammatory responses (in the process of neointimal hyperplasia). However, despite widespread clinical use of drug-eluting stents, in-stent restenosis remains a relevant challenge and unresolved problem.

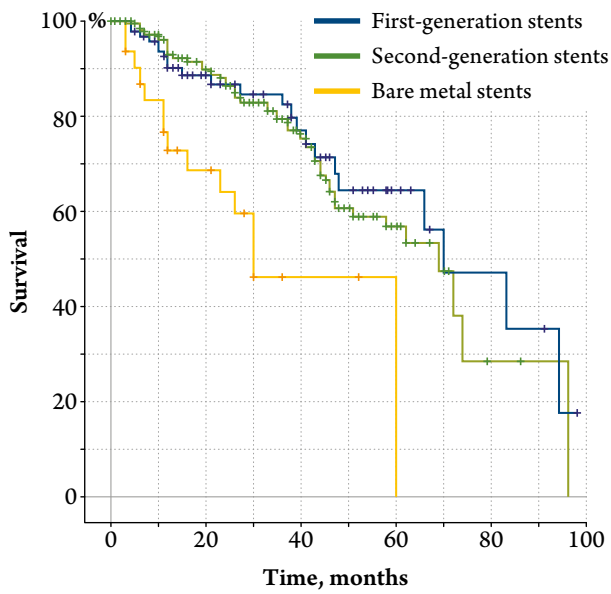
The long-term outcomes following the implantation of drug-eluting coronary stents were studied in many clinical registers. Numerous studies and data registers describe the best efficacy and safety profile, as well as short- and long-term prognoses after the implantation of second-generation stents in comparison with first-generation stents. According to 3- [10] and 5-year [11] follow-up, as opposed to first-generation stents, second-generation stents were associated with a lower rate of repeat revascularization of the target lesions. However, according to a 5-year observational study [12], the groups of patients with stented left main coronary artery and implanted first- and second-generations stents did not differ in the rate of repeat revascularization of the target lesions or the incidence of major cardiovascular complications. According to the 5-year follow-up study, the need for repeat revascularization of the target lesions

Figure 1. ROC curve for evaluation of the diagnostic significance of blood levels of high-sensitivity C-reactive protein in identifying restenosis of stents with a diameter <3 mm and a length >25 mm



CI, confidence interval.

Figure 2. Survival curve for patients with first-generation, second-generation, and bare-metal stents



after implantation of the first-generation sirolimus-eluting stents was low in the first year of follow-up; later, however, the rate of repeat revascularization of the target lesions did not decrease [13]. The findings of the long-term Swedish register of coronary angiography and angioplasty have been published recently, comparing the rates of stent restenosis and thrombosis after the implantation of the first-generation stents and BMSs. A year after the coronary stenting, the rate of restenosis and thrombosis of first-generation stents was significantly lower than that of BMSs. However, in a longer period of follow-up (mean duration >6 years), restenosis and thrombosis of first-generation stents were registered significantly more often [14].

In this study, we compared the time to return visit with restenosis of different stents that were implanted at our facility. The median time to the return visit of patients with first-generation stent restenosis was in the second to third year after the intervention. In contrast, the follow-up period in earlier studies with high rates of angiographic control did not usually exceed 12 months [15–17], which is consistent with more recent studies [10, 13, 14]. Worse outcomes after the implantation of first-generation stents versus second-generation stents may be due to differences in the composition of metal struts, the amount of antiproliferative coating, and polymer thickness. First-generation stent struts are made of alloys (nickel proportion of 20%), causing severe hypersensitivity, and second-generation stents have thinner struts, which contain cobalt and chromium and are much less likely to cause hypersensitivity (4% and 7%, respectively) [18, 19]. The thickness of the polymer coating in second-generation stents is less than in first-generation stents [20]. It was also demonstrated that the stent polymer could serve as an antigen, contributing to chronic inflammation in the vascular wall after the implantation of a drug-eluting stent [21]. First-generation stents were associated with late endothelialization of the stent surface and more severe toxicity of the polymer and drug coating, which caused hyperresponsiveness [22, 23]. More advanced antiproliferative agents and polymers used in second-generation stents contribute to better biocompatibility, which results in a less severe inflammatory reaction, more uniform elution of the antiproliferative agents, and better endothelialization of the stent's inner surface [24]. Experimental studies described the high severity of vascular inflammatory reactions in first-generation stents, characterized by peristrut inflammation and cellular infiltration [25, 26]. Yeh et al. [27] compared the incidence and severity of inflammatory reactions in first- and second-generation stents and BMSs of coronary arteries in pigs. Mean thickness of neointima in drug-eluting stents was significantly less than in BMSs; neointimal proliferation and the rate of formation of peristrut granulomas were less pronounced in second-generation stents than in first-generation stents.

Many authors have considered restenosis of the stented segment to be a consequence of the protracted inflammatory reaction in the stented region. The relationship between the probability of restenosis and the blood levels of various inflammatory markers (hs-CRP, monocyte chemotactic protein-1, myeloperoxidase, cardiotrophin-1, interleukin-6, platelet activation parameters) was shown [28–31]. Several studies [32–34] proved that the elevated levels of hs-CRP in pre-, peri-, and postintervention periods was a risk factor for in-stent restenosis. The meta-analysis of six prospective studies including 1,156 patients with CAD (a total of 885 stents implanted, in-stent restenosis is registered in 194 cases) showed that high levels of hs-CRP were associated with an increased risk for in-stent restenosis within 6–12 months and determined worse prognosis for this category of patients after coronary stenting [35]. In this study, the repeat blood levels of hs-CRP ≥2 mg/L was a predictor of restenosis of stents with a diameter <3 mm and a length >25 mm.

Elevated serum levels of LDL is an established risk factor for cardiovascular diseases due to atherosclerotic process and their subsequent progression [36]. Reducing LDL levels is associated with improved prognosis in patients after myocardial coronary stenting. However, even when the target LDL levels decrease, possible risks are still present. Thus, aggressive reduction of the LDL levels and the achievement of the target values are not sufficient to fully control the possible risk of cardiovascular complications. We were unable to identify the protective levels of LDL, although the target values were achieved by the time of the return visit in less than 25% of the total follow-up group.

In several large prospective randomized studies, second-generation stents demonstrated a lower rate of thrombosis [37, 38]. A meta-analysis of randomized controlled studies demonstrated a lower rate of stent thrombosis after the implantation of second-generation stents in patients with acute myocardial infarction than after implantation of first-generation stents.

However, there was no statistically significant benefit in reducing the rate of repeat revascularization of the target lesions [39]. In our study, we analyzed only the planned return visits to the Russian National Cardiology Research Center; it would be incorrect to compare the rate of stent thrombosis with data from other registers.

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Conclusion

The time from coronary stenting to the return visit of patients presenting with restenosis after the implantation of first- and second-generation drug-eluting stents is consistent; median time of the return visit of patients with restenosis of first-generation stents was 2–3 years after coronary stenting. Blood levels of high-sensitivity C-reactive protein ≥2 mg/L at the return visit is a predictor of restenosis of stents with a diameter <3 mm and a length >25 mm.

No conflict of interest is reported.

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