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COMPARISON OF A NOVEL BIODEGRADABLE STENT MAGMARIS WITH DRUG ELUTING RESOLUTE ONYX STENT: SAFETY AND 12 MONTH OUTCOMES

Resume: *stent implantation is effective method of overcome critical vessel narrowing and restore normal flowing of blood in affected ones in patients with coronary artery disease. Using biodegradable stent platform was the next step of treatment evolution and innovative idea for reducing complication.*
Purpose of the study: : to determine and compare the efficacy, safety and outcomes of implantation of a biodegradable Magmaris and drug eluting Resolute Onyx stent in patients with coronary artery disease in 12-month follow-up.
Material and methods: *The single-center prospective study included 50 patients with coronary heart disease who underwent stent implantation (Magmaris, main group – 25 patient, Resolute Onyx, control group - 25 patient). Inclusion criteria: verified coronary artery lesion by angiographic method, signed voluntary informed consent of the patient to participate in the study. The exclusion criteria: the presence of chronic occlusion of the coronary vessel, calcification, acute myocardial infarction, restenosis of a previously implanted stent.*
Results: *after stent implantation there were statistically approved positive dynamic both in severity of angina pectoris signs and in severity of heart failure (p=0.002 and p=0.012 respectively). Evidence of the first endpoints was only in Resolute Onyx group where in 1 case occurred stroke after 12 month of implantation (n=1, p=0.625). Death and myocardial infarction were not recorded. Two patient developed restenosis (8%) after stenting in main group (p=0.422), thrombosis was documented in both groups: one case after Magmaris and two cases after Resolute Onyx implantations (p=0.512).*
Conclusion: *using of biodegradable Magmaris and drug eluting Resolute Onyx stents demonstrated good clinical effects and comparable efficacy and safety in patients with coronary artery disease in 12-month follow-up.*
Keywords: *coronary heart disease, bioresorbable stents, drug eluting stents, endovascular methods of treatment*

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СРАВНЕНИЕ БИОДЕГРАДИРУЕМОГО СТЕНТА НОВОГО ПОКОЛЕНИЯ MAGMARIS СО СТЕНТОМ С ЛЕКАРСТВЕННЫМ ПОКРЫТИЕМ RESOLUTE ONYX: БЕЗОПАСНОСТЬ И ИСХОДЫ В ТЕЧЕНИЕ 12 МЕСЯЦЕВ НАБЛЮДЕНИЯ

Резюме: стентирование коронарных артерий является эффективным методом лечения критического стеноза сосудов и восстановления нормального кровотока у пациентов с ишемической болезнью сердца. Применение биодеградируемых стентов является следующим этапом в эволюции методов лечения и инновационной идеей для снижения осложнений.

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ЖАҢА БУЫНДАҒЫ БИОДЕГРАДАЦИЯЛАНАТЫН MARMARIS СТЕНТІН RESOLUTE ONYX ПРЕПАРАТЫМЕН ҚАПТАЛҒАН СТЕНТПЕН САЛЫСТЫРУ: 12 АЙЛЫҚ БАҚЫЛАУ КЕЗІНДЕГІ ҚАУІПСІЗДІК ЖӘНЕ НӘТИЖЕЛЕР

Түйін: коронарлық артерияларды стенттеу - ишемиялық жүрек ауруы бар науқастарда тамыр стенозын емдеудің және қалыпты қан ағымын қалпына келтірудің тиімді әдісі. Биодеградацияланатын стенттерді қолдану емдеу эволюциясының келесі кезеңі және асқынуларды азайтудың инновациялық идеясы болып табылады.
Мақсаты: 12 айлық бақылау кезінде жүректің ишемиялық ауруы бар науқастарда биодеградацияланатын Marmaris стенті

Цель: установить и сравнить эффективность, безопасность и исходы имплантации биодеградируемого стента Magmaris и стента с лекарственным покрытием Resolute Onyx у пациентов с ишемической болезнью сердца в течение 12-ти месячного наблюдения.
Материалы и методы: было проведено одноцентровое проспективное исследование с включением 50 пациентов с ишемической болезнью сердца, которым было проведено стентирование (Magmaris, основная группа – 25 человек, Resolute Onyx, группа сравнения – 25 человек). Критериями включения явились: верифицированое поражение коронарных артерий ангиографическим методом, подписанное добровольное информированное согласие пациента на участие в исследовании. Критериями исключения были наличие хронической окклюзии коронарного сосуда, кальциноз, острый инфаркт миокарда, рестеноз ранее имплантированного стента.
Результаты: после стентирования наблюдалось статистически значимая положительная динамика как в выраженности симптомов стенокардии напряжения, так и тяжести сердечной недостаточности (p=0.002 and p=0.012 respectively). События первичной конечной точки были только в группе Resolute Onyx, где у 1 пациента развился инсульт через 12 месяцев после стентирования (n=1, p=0.625). Случаев смерти и инфарктов миокарда не было. В основной группе наблюдался рестеноз у 2 пациентов (8%, p=0.422), тромбоз был в обеих группах: 1 случай после имплантации Magmaris и 2 случая после стентирования Resolute Onyx (p=0.512).
Заключение: применение биодеградируемого стента Magmaris и стента с лекарственным покрытием Resolute Onyx у пациентов с ишемической болезнью сердца продемонстрировало хорошие клинические эффекты и сопоставимую эффективность и безопасность в течение 12-ти месячного наблюдения.
Ключевые слова: ишемическая болезнь сердца, стенты с лекарственным покрытием, биодеградируемые стенты, эндоваскулярное лечение

мен Resolute Onyx препаратымен қапталған стентпен имплантациялаудың тиімділігін, қауіпсіздігін және нәтижелерін анықтау және салыстыру.
Жабдықтар мен әдістер: стенттеу жүргізілген жүректің ишемиялық ауруы бар 50 пациентті қамтитын бір орталықты перспективалық зерттеу жүргізілді (Magmaris, негізгі топ-25 адам, Resolute Onyx, салыстыру тобы – 25 адам). Зерттеу жүргізу критерийлері: коронарлық артериялардың зақымдалуының ангиографиялық әдіспен анықталуы, пациенттің зерттеуге қатысуға ерікті түрде хабардар етілген келісімі. Зерттеуге қарсы критерийлер: созылмалы коронарлық окклюзияның болуы, кальциноз, жедел миокард инфарктісі, бұрын имплантацияланған стенттің рестенозы болды.
Нәтижесі: стенттеуден кейін күштемелі стенокардия симптомдарының айқындығында да, сондай-ақ ауыр жүрек жеткіліксіздігі кезінде статистикалық маңызды оң динамика байқалды (p=0.002 and p=0.012 respectively). Бастапқы соңғы нүктедегі оқиғалар тек Resolute Onyx тобында болды, онда 1 пациент стенттеуден кейін 12 айдан кейін инсульт алды (n=1, p=0.625). Өлім жағдайлары мен миокард инфарктісі болған жоқ. Негізгі топта 2 пациентте рестеноз байқалды (8%, p=0.422), тромбоз екі топта да болды: Magmaris имплантациясынан кейінгі 1 жағдай және Resolute Onyx стентінен кейінгі 2 жағдай (p=0.512).
Қорытынды: жүректің ишемиялық ауруы бар пациенттерде биодеградацияланатын Magmaris стенті және Resolute Onyx препаратымен қапталған стентті қолдану 12 айлық бақылау кезінде жақсы клиникалық әсерлер мен салыстырмалы тиімділік пен қауіпсіздікті көрсетті.
Түйінді сөздер: жүректің ишемиялық ауруы, дәрі-дәрмекпен қапталған стенттер, биодеградацияланатын стенттер, эндоваскулярлық емдеу.

Coronary artery disease (CAD) is a common type of cardiovascular pathology and the third cause of mortality in the World [1]. Nowadays stent implantation is effective method of overcome critical vessel narrowing and restore normal flowing of blood in affected ones in patients with CAD [1, 2]. There are several types of implanted cardiovascular stents: the evolution of this devices starts from bare-metal and ends by novel biodegradable ones. Construction of the first generation of cardiovascular stents was simpler and there was made by non-corrosive metal (stainless steel, tantalum, nitinol, cobalt-chromium). Restenosis and target lesion revascularization after bare-metal stent implantation was about 16%-20% [3]. So, drug eluting stents was the next step of improving stent technology in interventional cardiology. This type of stents have special coating drug eluting polymer on thinner stent struts, which help in reducing inflammatory and proliferation in affected vessels and to avoid restenosis [2-7]. There are four generation of such types of coronary stents, which includes different drugs: sirolimus, paclitaxel, everolimus, zotrolimus, biolimus, probucol, novolimus. Thinner struts help to minimize vascular injury, increase endothelialization and decrees trombogenicity. However, results of clinical trials shows such complication like stent thrombosis and target-lesion revascularization in about of 0.8% and 4.9% respectively (GLOBAL LEADER trial), 1.0% and 2.0% respectively (SENIOR trial), 2.0% and 5.1% of cases respectively (LEADER FREE trial). However, in these results was shown statistically significant lower rate of target-lesion revascularization in comparison to bare metal stents while rate of bleeding was the same – about 2-7.2% [8].

Using biodegradable stent platform instead of metallic ones was creative and innovative idea for reducing complication. The main mechanism of that is gradual degrading of stent after total drug eluting in target coronary artery, which can decries mechanical stress in target vessel for its bet-

ter recovery [2, 9-13]. This type of stents open new perspectives in interventional cardiology and should be studied better for improving patient selection for implantation and better prognosis.

The aim of study: to determine and compare the efficacy, safety and outcomes of implantation of a biodegradable Magmaris stent (Biotronik, Switzerland) and drug eluting Resolute Onyx stent (Medtronic, USA) in patients with CAD in 12-month follow-up.

Materials and methods: Study population and devises in the study: we conducted a single-center prospective study with sequential inclusion of patients with coronary heart disease who underwent implantation of a biodegradable Magmaris stent (Biotronik, Switzerland) from November 1, 2019 to December 2021 (main group). The control group consisted of patients with implanted drug eluting Resolute Onyx stent (Medtronic, USA). Inclusion criteria were: verified coronary artery lesion by angiographic method, signed voluntary informed consent of the patient to participate in the study. The exclusion criteria were the presence of chronic occlusion of the coronary vessel, calcification, acute myocardial infarction, restenosis of a previously implanted stent. This study was carried out in accordance with the principles of the Declaration of Helsinki and approved by the Local Ethics Committee. In addition to general clinical studies, all patients underwent lipid spectrum assessment, electrocardiogram, and echocardiography. Dynamic observation was carried out for 12 months with an assessment of the patency of the coronary arteries by the angiographic method. Endpoints and outcomes: The primary endpoint of observation was: death from any causes, cerebrovascular and cardiovascular events. The secondary endpoint of observation was the development of restenosis and late thrombosis. The data were evaluated during the observation period with a comparative analysis in both study groups.

Statistical analysis: Statistical analysis was performed using IBM SPSS Statistics version 20.0 (IBM, USA). The main variables for the analysis were the clinical parameters of patients - age, gender, comorbidities, the presence of risk factors for cardiovascular diseases, the class of heart failure, the affected coronary artery, the extent of the vascular lesion, the duration and volume of radiological exposure, the presence of restenosis, cerebral and cardiovascular diseases, events during the observation period. The display of quantitative variables is represented by the calculated Median (Me) and standard deviation (Standart deviation, SD), qualitative variables are indicated as absolute numbers with the calculation of the percentage as a percentage. The revealed differences were considered statistically significant at the calculated value equal to $p<0.05$.

Results: The total number of observations was 25 cases of implantation of the biodegradable Magmaris stent in patients with coronary heart disease aged from 41 to 84 years (main group) and 25 cases of drug eluting Resolute Onyx implantation in patients with coronary heart disease aged from 46 before 81 years (control group). The median age of patients in the main and control groups were 62.4±6.3 years and 65.7±7.5 years, respectively ($p = 0.078$), men – 22(88%) and 19 (76%), women – 3 (12%) and 6 (24%) respectively ($p=0.145$). The distribution by age groups in the main group was as follows: in the group of 40-49 years old, there were 2 men (9.09%), in the group of 50-59 years old -7 men (31.8%) and 2 women (66.6%), 60-69 years old - 9 men (40.9%), over 70 years old - 4 men (18.1%) and 1 female (33.3%). Moreover, the distribution by age groups in the control group was as follows: in the group of 40-49 years old, there were 2 men (10.0%), in the group of 50-59 years old - 4 men (21.0%) and 2 woman (33.3%), 60-69 years old - 84 men (42.1%), over 70 years old - 5 men (26.3%) and 4 woman (66.6%).

The main clinical characteristics of patients, such as comorbidities, previous cardiovascular events according to the anamnesis, the severity of symptoms of angina pectoris according to the classification of the Canadian Cardiovascular Society (CCS), the presence heart failure with an indication of the class according to the classification of the New York Heart Association (NYHA), features of drug therapy - the appointment and use of dual antiplatelet therapy, lipid-lowering therapy are presented in Table 1.

The most common coronary vessel for implantation of the Magmaris stent (n=25) were the right coronary artery in 13 (52%) cases and left anterior descending artery 12 (48%) patient, for the Resolute Onyx stent were the right coronary artery 10 (40%) cases, left anterior descending artery 12 (48%) patient and left circumflex artery in 3 (12%) cases ($p=0.758$). The mean stent diameter in study and control groups were 3.25±0.25mm and 3.21±0.25mm respectively ($p=0.351$), the mean length of device were 21.2±2.3mm and 22.2±3.3mm respectively ($p=0.282$).

An analysis was also made of the dynamics of the severity of symptoms of angina pectoris according to the classification of the Canadian Society for the Study of Cardiovascular Diseases (Canadian Cardiovascular Society, CCS) and changes in the severity of manifestations of heart failure according to the classification of the New York Heart Association (NYHA) after the implantation of biodegradable stents and drug eluting Resolute Onyx stent (Table 2).

Further postoperative follow-up was carried out for 12 months. During the follow-up period for patients after implantation of biodegradable stents and drug eluting Resolute Onyx stent, the developed complications, development of restenosis, cerebral and cardiovascular events were assessed. Thus, such complications as patient death and myocardial infarction were not recorded. Two patient developed restenosis (8%) after stenting in main group ($p=0.422$), thrombosis was documented in both groups: one case after Magmaris and two cases after Resolute Onyx implantations ($p=0.512$) (Table 3).

Discussion: According our results the prevalent age and gender of patients in both group was comparable and were mostly man (76-88%) at about 62.4-65.7 years of age ($p=0.145$ and $p=0.078$ respectively). This results is comparable with data of Boeder N.F., Dörr O., Koepp T. et al. study, where enrolled patients were relatively young

Table 1 - Clinical characteristics of patients

	Magmaris (n=25)		Resolute Onyx (n=25)		p
	n	%	n	%	
Comorbidities and risk factors:					
Arterial hypertension	18	72	18	72	0,752
Hypercholesterolemia	17	68	18	72	0,695
Diabetes	7	28	7	24	0,752
Smoking	7	28	7	20	0,752
COPD	1	4	1	4	0,756
Myocardial infarction within <90 days	1	4	0	0	0,548
Cerebrovascular diseases	8	32	7	28	0,562
Peripheral artery disease	6	24	6	24	0,755
Body mass index:					
< 18.5	0	0	0	0	-
18.5 – 24,9	3	12	7	28	0,012
25 – 29,9	12	60	6	24	0,002
30-34,9	7	16	8	32	0,385
35-39,9	3	12	4	16	0,432
40 and more	0	0	0	0	-
Functional class of angina pectoris (CCS)					
I	0	0	0	0	-
II	0	0	0	0	-
III	25	100	25	100	0.796
IV	0	0	0	0	-
Class of heart failure (NYHA)					
I	0	0	0	0	-
II	5	20	2	8	0,785
III	20	80	23	92	0,722
IV	0	0	0	0	-
Drug therapy					
DAT	23	92	25	100	0,446
Statins	23	92	23	92	0,765

COPD – chronic obstructive pulmonary disease, DAT – dual antiplatelet therapy, NYHA – New York Heart Association, CCS-Canadian Cardiovascular Society

Table 2 - Dynamics of the severity of symptoms of angina pectoris and heart failure during the observation period after stenting in the main and control groups

	Magmaris (n=25)			Resolute Onyx (n=25)		
	Before (n/%)	After (n/%)	p	Before (n/%)	After (n/%)	p
Functional class of angina pectoris (CCS)						
I	0	25	0.002	0	25	0.002
II	0	0		0	0	
III	25	0		25	0	
IV	0	0		0	0	
Class of heart failure (NYHA)						
NYHA I	0	25	0.012	0	25	0.012
NYHA II	5	0		2	0	
NYHA III	20	0		23	0	
NYHA IV	0	0		0	0	

Table 3 - Complications after stenting

	Magmaris (n=25)		Resolute Onyx (n=25)		p
	n	%	n	%	
Death	0	0	0	0	-
Myocardial infarction	0	0	0	0	-
Stroke	0	0	1	4	0,625
Restenosis	2	8	0	0	0,422
Thrombosis	1	4	2	8	0,512

(62±8.1 and 61.7±8.9 years), but only in Magmaris group was significantly more female gender (68.4%, p=0.01) [10]. In data of Rola P., Włodarczak A., Włodarczak S. et al. the characteristic of enrolled population were almost the same: the mean age in the range 66.3±8.9 and 65.2±9.34 years (p=0.605) with prevalence of man in both groups (77.7% vs 75.7%, p=0.481) [11]. Studying the frequency of risk factors shows that there was no statistically significance between two our groups (arterial hypertension, hypercholesterolemia, diabetes, smoking) (p>0.05). The most common comorbid disease was arterial hypertension, which was documented in 72% of patients in both groups (p=0.752). Hypercholesterolemia was also common and diagnosed in 68% of patients in Magmaris and 72% of patients in Resolute Onyx groups (p=0.695). The study of range of body mass index revealed some differences. Despite the number of patient with overweight was significantly higher in study group (60%, p=0.002), the amount of patients with the 1st and 2nd degrees of obesity were the same in both groups: 16% vs 32% of the 1st degree respectively, p=0.385, 12% vs 16% of the 2nd degree respectively, p=0.432. Thus, in total 88% of patient in Magmaris group and 72% of patient in Resolute Onyx group had overweight. Our results is totally agree with consensus of more common risk factors in patients with chronic coronary syndromes published in European guidelines [1].

In studying of clinical signs of angina pectoris according to the classification of the Canadian Cardiovascular Society (CCS) was found that the III class of symptoms diagnosed in all patients of both groups (p=0.796). Moreover, severity of heart failure according to the classification of the New York Heart Association (NYHA) was mostly high in both groups without statistically significance: the III class in 80% and 92% of cases (p=0.722) and the II class only in 20% and 8% respectively (p=0.785). However, after stent implantation there were statistically approved positive dynamic both in severity of angina pectoris signs and in severity of heart failure. Thus, all patients after Magmaris and Resolute Onyx implantation reduced to the I functional class of angina pectoris (CCS) (p=0.002) and to the I class of heart failure (NYHA) (p=0.012). This data demonstrated excellent clinical effects of this procedure and correlated with recommendation of European guidelines [1].

Evidence coming from procedural characteristics showed the same rate of target vessels and device characteristics in Magmaris and Resolute Onyx groups (p>0.05). This result almost agree with C.Rapetto and M.Leoncini dates, were left anterior descending artery was damaged in 44% vs 52% of cases, right coronary artery – 36% vs 28%, circumflex artery – in 20% (p=0.66) [9]. Boeder N.F., Dörr O., Koepp T. et al. study foundlings were almost the same: target vessels were mostly right coronary artery – 47.4% vs 41.8%, then left anterior descending artery – in 31.6% vs 35.4% and circumflex artery – 15.8% vs 22.8% (p=0.78) [10]. The stent diameter and length also was comparable with these results [9, 10]. Therefore, target vessel and device characteristic were comparable in both our groups and it agrees with other studies with similar design.

Reviewing the further course of disease was found that evidence of the first endpoints was only in Resolute Onyx group (n=1, p=0.625). In this man of 62 year old was documented stroke after 12 month of implantation. The other outcomes of the first endpoints like death of any reasons and myocardial infarction were not registered in patients of both groups. Our results in Magmaris group were better than in published reports of Bossard M., Madanchi M., Avdijaj D. et al. [13]. According their report there were 1.2% of cardiac death in 6 month and 1.2% in 1 year after procedure, target vessel myocardial infarction was documented in 3.6% of cases in 6 month and 4.9% of patient in 1 year after implantation [13]. According dates of RESOLUTE China registry cardiac death at 5 years outcome complete 3.5%, non-cardiac death – 3.1%, , target vessel myocardial infarction – 3.2%, cardiac death of target vessel myocardial infarction – in 6.1% of cases [4]. Rola P., Włodarczak A., Włodarczak S. et al. showed in there article next outcomes after bioresorbable stents implantation: 1% of 1 year death of any reason and absents of cardiac death in follow up, target vessel myocardial infarction in 1% of cases in Magmaris and 3% in Ultimaster patients (p=0.259) [11]. Thus, all enrolled patients of both our groups have demonstrated comparable results in achieving the first endpoints, which was better than in published results in such indicators like death of any reason and target vessel myocardial infarction.

Results of analysis of the second endpoints were without statistical significance in Magmaris and Resolute On-

yx groups while restenosis was only in patients of study group (p=0.422). By the date of follow-up after implantation there were 2 cases of restenosis only in Magmaris group. In one male patient aged 72 years was diagnosed 95% occlusion of coronary artery in 12 month after procedure of stent implantation. In this case there were many risk factors: comorbidities (arterial hypertension, diabetes, dyslipidemia, smoking, cerebrovascular disease, previous percutaneous coronary interventions). The second patient was with documented 60% of coronary artery occlusion in 12 month after Magmaris implantation. This patient of 71 age had some comorbidities like arterial hypertension, diabetes (insulin suffering), multifocal atherosclerosis and also had history of previous revascularization. Thus, our results of the rate of restenosis after Magmaris implantation (8%) is almost agree with Bossard M., Madanchi M., Avdijaj D. et al. datas (6.1% at 6 month, 8.5% at 1 year) [13]. However, according the dates of Rola P., Włodarczak A., Włodarczak S. et al. the rate of restenosis after bioresorbable stents implantation at 1 year follow up was lower than in our study and complete 1% in both Magmaris and Ultimaster groups [11]. While there was no cases of restenosis in Resolute Onyx groups of our study in Torii S., Jinnouchi H., Sakamoto,A. et al. reports was shown 4.9% and 5.1% of target-lesion revascularization in 2 and 1 year after drug eluting stent implantation respectively [8].

Cases of thrombosis were in both groups (p=0.512). Thrombosis occurred in one patient in Magmaris group after 2 month of implantation. This patient was at 63 year and did not use dual antiplatelet therapy which was recommended after implantation. There were two cases of thrombosis in Resolute Onyx groups after 1 and 4 month of implantation despite using of dual antiplatelet therapy. In one patient of 49 years old with arterial hypertension, diabetes who smoked a long period of time occurred thrombosis after 4 month of Resolute Onyx implantation. The second case was in man of 63 years old, suffering from arterial hypertension, diabetes with insulin therapy, dyslipidemia. The rate of thrombosis after drug eluting stent implantation in our study was higher than in published review of Torii S., Jinnouchi H., Sakamoto A. et al. (8% versus 1.9% at 1-2 years) and data's of Qiao S., Chen L., Chen S.L. et al. (0.5% at 5 years) [4, 8]. In Magmaris group the rate of thrombosis in our study (4%) was almost the same as in Bossard M., Madanchi M., Avdijaj D. et al. reports (3.6% at 6 month, 4.9% at 1 year) [13]. This outcome also can be due to violation of treatment in one case – absents of dual anti-platelet therapy. Thus, there are 3 cases of late thrombosis in both Resolute Onyx and Magmaris groups in our study that is supported by the results of other authors.

Limitations: The most significant limitation of our study is the small size of the observation groups, which requires further trials and the inclusion of more patients in this study with randomization to increase the statistical significance of the results.

Conclusion: using of biodegradable Magmaris and drug eluting Resolute Onyx stents demonstrated good clinical effects. At 1 year follow-up there is low clinical event rate in both studying groups. These outcomes demonstrated comparable efficacy and safety of biodegradable Magmaris stent (Biotronik, Switzerland) and drug eluting Resolute Onyx stent (Medtronic, USA), which require further analyses of data in larger cohort.

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