In-hospital and mid-term clinical outcomes after percutaneous coronary intervention with the use of sirolimus- or paclitaxel-eluting stents

Mohammad Alidoosti[1], Mojtaba Salarifar[1], Seyed E. Kassaian[1], Ali M. Haji Zeinali[1], Ebrahim Nematipoor[1], Mahmood Sheikhfathollahi[2], Hamidreza Poorhosseini[1], Maria Raissi Dehkordi[2], Ali Abbasi[1, 3]

[1] Department of Cardiology, Tehran Heart Center, Tehran University of Medical Sciences, Tehran, Iran

[2] Department of Cardiovascular Research, Tehran Heart Center, Tehran University of Medical Sciences, Tehran, Iran

[3] Department of Epidemiology, University Medical Centre Groningen, Groningen, Netherlands

Abstract

Background: Drug-eluting stents improved the outcome after percutaneous coronary intervention (PCI), however, there may be significant differences in their safety and efficacy.

Aim: To compare the in-hospital and mid-term clinical outcomes of stenting with sirolimus-eluting stents (SES) versus paclitaxel--eluting stents (PES) for the treatment of coronary artery lesions in our routine practice.

Methods: This study was performed on 1311 consecutive patients treated exclusively either with SES or PES in our hospital between March 2003 and March 2007. Patients with acute myocardial infarction (MI) within the preceding 48 hours were excluded. The data were recorded in our computerised database, and analysed with appropriate statistical methods.

Results: The frequency of angulated segments and proximal segment tortuosity was higher in the PES group ($p = 0.001$ and $p < 0.001$, respectively), while ostial and left anterior descending artery lesions were more frequently treated with SES ($p < 0.001$ and $p = 0.022$, respectively). The rate of in-hospital non-Q wave MI was higher in the SES vs. PES group (2.2 vs. 0.7%, $p = 0.039$). In multivariate analysis, the relationship between type of stent and in-hospital non-Q-wave MI became less significant ($p = 0.083$). During follow-up, 5 patients in the SES vs. 3 in the PES group died (0.7% in each group, $p = 0.749$). The frequency of major adverse cardiac events (MACE) and target vessel revascularisation (TVR) in the SES vs. PES group was similar (5.5 vs. 3.3%, $p = 0.138$, and 2.9 vs. 1.6%, $p = 0.213$, respectively). In multivariate analysis, reference vessel diameter was an independent predictor of both TVR (HR = 0.170, 95% CL 0.034-0.837, $p = 0.029$) and MACE (HR = 0.333, 95% CL 0.120-0.925, $p = 0.035$).

Conclusion: During mid-term follow-up, sirolimus-eluting stents and paclitaxel-eluting stents demonstrate similar clinical outcomes.

Key words: sirolimus-eluting stents, paclitaxel-eluting stents, clinical outcome

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Introduction

Coronary stenting has led to the improvement of outcomes in patients undergoing percutaneous coronary intervention (PCI). Drug-eluting stents have brought a revolution in the field of PCI by significantly reducing the occurrence of restenosis, the need for revascularisation, and major adverse cardiac events (MACE) compared with bare metal stents in short-term and long-term follow-up [1-5]. The sirolimus-eluting stents (SES) (Cypher, Cordis, Johnson and Johnson, Miami Lakes, Florida) and paclitaxel-eluting stents (PES) (TAXUS, Boston Scientific Corp., Natick, Massachusetts) are the most studied drug-eluting stents thus far. However, their mechanism of action is different; sirolimus is an immunosuppressive drug with anti-inflammatory properties, producing cell-cycle arrest in the G1/S phase transition, while paclitaxel is an antineoplastic drug that causes cell-cycle arrest in the G2/M phase transition and is considered as a cytotoxic agent [6, 7]. Moreover, these 2 systems differ in stent design and polymer, raising the question whether there is any difference between them for the purpose of PCI.

The results from randomised comparisons between these two stent types have been inconclusive. For instance, although some studies have reported a higher rate of MACE and

Address for correspondence:
Mohammad Alidoosti MD, Department of Cardiology, Tehran Heart Center, Tehran University of Medical Sciences, North Kargar Street, Tehran Heart Center, Tehran, 1411713138, Iran, tel./fax: +98 21 880 292 56, e-mail: alidoostitums@gmail.com

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restenosis with PES [8, 9], other studies have shown similar results [10, 11]. This has been partly because of the differences in the populations studied, implantation and angiographic techniques applied, and methods of data analysis.

In this study, we aimed to compare the mid-term outcomes of stenting with these two stent types in a consecutive population. Although these patients were not randomly assigned, they were treated exclusively either with SES or PES in our routine clinical practice according to stent availability and operators' discretion.

Methods

Study population

This study group consisted of 1311 consecutive patients who had coronary artery disease and were treated either with SES or PES according to stent availability and operators' discretion in our hospital between March 2003 and March 2007. The type, length and number of coronary lesions did not influence the choice of stent. The data were extracted from a prospective computerised registry of patients (PCI-IR database) at our centre with more than 2100 procedures per year performed by six expert operators. Baseline clinical, angiographic, and procedural characteristics and in-hospital outcomes were obtained by research physicians and entered into a computerised database by computer operators. Clinical outcomes, most importantly major adverse cardiac events (MACE), were obtained in clinics, or by formal telephone interviews, at 1 month, 6 months, 12 months, and once yearly thereafter and recorded in datasheets, which were later entered into our computerised database. In our study, only patients treated exclusively either with SES or PES were included. Patients with acute myocardial infarction (MI) within the preceding 48 h of the procedure were excluded. This study was approved by the Institutional Ethics Committee according to the Declaration of Helsinki, as revised in 2000, and written informed consent was obtained from all patients for enrolment in the study.

Angioplasty procedures

All procedures were done with a 6 or 7 French gauge guiding catheter and a femoral approach. Treatment with aspirin began 12 h or more before the procedure in a dose of at least 100 mg. Clopidogrel was administered before the procedure in a loading dose of 300 mg followed by 75 mg once daily or in a maintenance dose of 75 mg for 3 or more days before the procedure. Alternatively, 2 doses of ticlopidine, 250 mg, were administered within 24 hours before the myocardial revascularisation procedure. At the procedure, heparin was administered in boluses to reach and maintain an activated clotting time of more than 250 s. In case of dissection or incomplete coverage of the lesion, additional DES stents were used as necessary. Stents were deployed with or without predilatation according to standard techniques. Stent length ranged between 13 mm and 38 mm in the SES and between 12 mm and 33 mm in the PES group. Stent diameter ranges were 2.5 – 4 mm in the SES and 2.25 mm to 3.5 mm in the PES group. Overlapping stents were used in a total of 35 patients: 27 with PES and 7 with SES. After stent implantation, aspirin (100 mg/day) was prescribed for indefinite duration and clopidogrel (75 mg/day) was administered for 6 to 12 months.

Definitions

Anginal symptoms were defined according to the classification of the Canadian Cardiovascular Society [12]. A Q wave MI was defined as the presence of new Q waves in the post-procedure ECG, with a 3-fold increase in MB fraction of creatine kinase. A non-Q wave MI was defined as a 3-fold increase in MB fraction of creatinine kinase without the development of new Q waves [13]. Angiographic success was defined as residual stenosis < 20% plus normal TIMI flow grade 3. Procedural success was defined as angiographic success without major complications (death, MI, emergency bypass surgery, or PCI) during hospitalisation.

Major adverse cardiac events were defined as cardiac death, non-fatal MI, or target vessel revascularisation (TVR). Target vessel revascularisation was defined as clinically driven percutaneous revascularisation or bypass of the target lesion or any segment of the epicardial coronary artery containing the target lesion. Target lesion revascularisation (TLR) was defined as any repeat revascularisation procedure (percutaneous or surgical) of the original target lesion site. The primary endpoint was to compare occurrence of MACE between both groups during follow-up and determine its independent predictors in the total population. As a secondary aim, we compared the in-hospital outcomes between these two groups.

Statistical analysis

Quantitative data are presented as the mean ± SD, and categorical data as the percentage.

Statistical analysis was performed using the chi-square or Fisher's exact test (2-tailed) for categorical variables. Student's t-test was used for comparison of continuous variables. Univariate and multivariate analyses of hazard ratios, including 95% confidence intervals, were calculated using the Cox proportional hazard method. Factors with p values < 0.15 in the univariate analysis were entered into the multivariate model. Univariate analyses were performed with the SPSS package (SPSS Version 13; SPSS, Chicago, IL). Multivariate analyses were conducted with the SAS software version 9.1.

Results

Patient and procedural characteristics

In our study, 1311 patients with 1455 lesions were treated with 936 SES and 557 PES. Table I shows that except for family history of coronary artery disease, other

Table I. Demographic and clinical characteristics of patients treated with sirolimus-eluting stents (SES) vs. paclitaxel-eluting stents (PES)

	SES group (n = 839)	PES group (n = 472)	p
Age [years]	55.3 ± 10.3	55.9 ± 10.5	0.356
Male, n (%)	609 (72.6)	345 (73.1)	0.843
Diabetes mellitus, n (%)	203 (24.5)	107 (22.8)	0.492
Family history of CAD, n (%)	212 (26)	155 (33.1)	0.002
Smoking, n (%)	161 (19.4)	119 (25.3)	0.013
Hyperlipidaemia, n (%)	434 (52.3)	253 (53.8)	0.593
Hypertension, n (%)	314 (37.8)	163 (38.9)	0.694
Prior PCI, n (%)	63 (7.5)	26 (5.5)	0.170
Prior CABG, n (%)	22 (2.6)	10 (2.1)	0.578
Stable angina, n (%)	304 (37.3)	213 (45.8)	0.003
Recent unstable angina, n (%)	142 (16.9)	34 (7.2)	< 0.001
Recent MI, n (%)	58 (6.9)	18 (3.8)	0.021

Abbreviations: CAD – coronary artery disease, PCI – percutaneous coronary intervention, CABG – coronary artery bypass grafting, MI – myocardial infarction

Table II. Angiographic and procedural characteristics of patients treated with sirolimus-eluting stents (SES) vs. paclitaxel-eluting stents (PES)

	SES group (n = 839)	PES group (n = 472)	p
Angiographic characteristics			
Type B2/C lesions, n (%)	673 (80.9)	387 (82.2)	0.570
Angulated segments (> 45°), n (%)	60 (7.2)	75 (15.9)	0.001
Diffuse lesion, n (%)	439 (52.3)	231 (48.9)	0.239
Bifurcation, n (%)	36 (4.3)	13 (2.8)	0.159
Proximal segment tortuosity, n (%)	227 (27.1)	219 (46.4)	< 0.001
Calcified lesion, n (%)	31 (3.7)	20 (4.2)	0.626
Thrombus, n (%)	19 (2.3)	10 (2.1)	0.863
Total occlusion, n (%)	62 (7.4)	35 (7.4)	0.986
RVD [mm]	2.95 ± 0.29	2.98 ± 0.29	0.52
Lesion length [mm]	23.58 ± 9.09	22.17 ± 10.01	0.069
Pre-procedural stenosis	88.01 ± 8.40	89.26 ± 8.05	0.604
Ostial lesion, n (%)	60 (7.2)	19 (4)	0.022
Left anterior descending artery, n (%)	673 (80.2)	326 (69.1)	<0.001
Procedural characteristics			
Stent length [mm]	26.02 ± 6.25	24.90 ± 5.93	0.001
Stent diameter [mm]	2.91 ± 0.27	2.95 ± 0.28	0.016
Stent inflation pressure [atm]	14.64 ± 2.99	13.65 ± 2.77	< 0.001
Direct stenting, n (%)	357 (42.6)	217 (46)	0.237

demographic characteristics were similar. Patients in the SES group were more likely to present with recent unstable angina and MI and less likely to present with stable angina.

Table II shows that the frequency of lesions with angulated segments and proximal segment tortuosity was higher in the PES group, while ostial and left anterior descending artery lesions were more frequently treated with SES. Lesions tended to be longer and have smaller diameters in the SES group; stent sizes also showed corresponding differences.

In-hospital outcomes

One patient from each group died in hospital: One day after the placement of a PES (2.5 × 24 mm, 12 atm 30 s)

Table III. In-hospital and long-term clinical outcomes in patients treated with SES and PES

	SES (n = 839)	PES (n = 472)	p
In-hospital outcomes			
Angiographic success, n (%)	835 (99.5)	472 (100)	0.557
Procedural success, n (%)	798 (97.5)	457(99.1)	0.011
Non-Q wave MI, n (%)	18 (2.2)	3 (0 .7)	0.039
In-hospital mortality, n (%)	1 (0.1)	1 (0.2)	> 0.999
Mid-term clinical outcomes	**SES (n = 761)**	**PES (n = 427)**	
Cardiac death, n (%)	5 (0.7)	3 (0.7)	0.749
Q-wave MI, n (%)	20 (2.6)	8 (1.9)	0.541
TLR, n (%)	14 (1.8)	3 (0.7)	0.161
CABG, n (%)	3 (0.4)	2 (0.5)	0.772
TVR, n (%)	22 (2.9)	7 (1.6)	0.213
MACE, n (%)	42 (5.5)	14 (3.3)	0. 138

Abbreviations: MACE – major adverse cardiac events, TLR – target lesion revascularisation, TVR – target vessel revascularisation

for a left circumflex artery lesion the patient developed malignant ventricular fibrillation. The other patient was treated with SES (2.75 × 33 mm, 12 atm 20 s) and developed sudden pulmonary oedema and respiratory distress due to aortic dissection, and cardiopulmonary resuscitation procedures were unsuccessful. Four cases of failure to pass either the guide wire (1) or the stent (3) occurred in the SES group, while all the procedures in the PES group were successful. The rate of in-hospital non-Q wave MI was lower in the PES group, which together with the higher angiographic success rate contributed to a higher procedural success rate in this group (Table III). We then constructed multivariate models to determine the independent predictors of non-Q-wave MI. These variables included type of stent, stable and recent unstable angina, hyperlipidaemia, diabetes mellitus, type B2/C lesions, total occlusions, single lesion PCI, diffuse lesions, severe proximal tortuosity, right coronary artery, and direct stenting. Multivariate analysis showed that hyperlipidaemia (OR = 4.780, 95% CI 1.368-16.708, p = 0.014) and diabetes mellitus (OR = 2.736, 95% CI 1.097-6.824, p = 0.031) were independent predictors for increased risk of in-hospital MI. However, the relationship between PES and in-hospital non-Q-wave MI was less significant (OR = 0.324, 95% CI 0.091-1.160, p = 0.083).

Mid-term outcomes

Eight patients were not included in the follow-up analysis: 2 patients who died in hospital, 4 patients in whom it was not possible to pass the guidewire or stent at the first place, and 2 patients who underwent emergent CABG. Hence, follow-up was conducted in a total of 1304 patients who had successful stent placement and had survived the period of hospitalisation without major complications. A total of 9% of patients were lost to follow-up after several telephone calls and mailing the patients' addresses.

During the follow-up period (16.7 ± 7 months), 5 patients from the SES vs. 3 from the PES group died (0.7% in each group, p = 0.749). One of the deaths was due to rapid progression of end-stage right-sided heart failure in the setting of pulmonary thromboembolism, and superimposed warfarin toxicity. Another patient expired due to MI 9 months after the procedure due to discontinuation of anti-platelet treatment. Univariate Cox regression analysis showed no difference in the outcomes of MACE and TVR in the SES vs. PES group (HR = 1.604, 95% CI 0.859-2.996, p = 0.138; and HR = 1.778, 95% CI 0.718-4.403, p = 0.214). We then adjusted these groups for confounding factors. The confounding factors for the relationship between stenting strategy and MACE were: diffuse, stable angina, recent MI/unstable angina, and reference vessel diameter. The confounding factors for the stenting group and TVR were: stable angina, recent MI/unstable angina, left anterior descending artery, and reference vessel diameter. The multivariate tests showed that the difference between the groups became even less significant for MACE and TVR in the SES vs. PES group after adjustment for these confounding factors (HR = 1.482, 95% CI 0.792-2.775, p = 0.219; and HR = 1.547, 95% CI 0.620-3.862, p = 0.350).

Independent predictors for MACE and TVR in the total population

We amalgamated the two groups treated with SES and PES in order to find independent predictors for these outcomes in the total population. Tables IV and V show the predictors of these two outcomes in univariate and multivariate analyses. As shown, the only independent predictor for the occurrence of both outcomes was reference vessel diameter.

Table IV. Predictors for target vessel revascularisation in univariate and multivariate analysis

	Univariate analysis			Multivariate analysis		
	Hazard ratio	95% CI	p	Hazard ratio	95% CI	p
Smoking	1.919	0.906-4.063	0.088	2.116	0.946-4.735	0.068
Stable angina	0.468	0.189-1.159	0.101	0.673	0.247-1.839	0.441
Recent MI/unstable angina	1.942	0.887-4.252	0.097	2.010	0.822-4.917	0.126
RCA	2.139	0.964-4.749	0.062	1.930	0.838-4.448	0.122
Diffuse lesion	1.965	0.905-4.269	0.0878	1.673	0.756-3.705	0.204
RVD	0.305	0.042-1.282	0.106	0.170	0.034-0.837	0.029

Abbreviations: RCA – right coronary artery, RVD – reference vessel diameter

Table V. Predictors for major adverse cardiac events in univariate and multivariate analysis

	Univariate analysis			Multivariate analysis		
	Hazard ratio	95% CI	p	Hazard ratio	95% CI	p
Calcified lesion	2.379	0.852-6.673	0.098	2.402	0.857-6.734	0.096
Stable angina	0.565	0.307-1.038	0.066	0.627	0.335-1.173	0.144
Recent MI	2.046	0.875-4.783	0.098	1.927	0.805-4.617	0.141
Diffuse lesion	1.583	0.922-2.719	0.096	1.469	0.849-2.542	0.169
RVD	0.343	0.126-0.936	0..037	0.333	0.120-0.925	0.035

Abbreviations: as in Table IV

Discussion

The most important finding of this study is that there is no difference between SES and PES in terms of clinical MACE and its constituent components, before and after adjustment for confounding factors, in the setting of our routine practice. Our results also showed that following adjustment with Cox regression models, the hazard ratio for MACE in the SES vs. PES group became closer to unity, compared with the unadjusted results. In this setting, the only predictor for these outcomes was reference vessel diameter.

In this study, PES was more frequently used in lesions with more complex structures such as angulated segments and proximal segment tortuosity, due to our own experiences and reports about its better flexibility and deliverability [14]. As shown in Table III, all the procedures were angiographically successful in the PES group, in contrast to 4 failure cases in the SES group. This, together with the lower rate of non-Q wave MI, contributed to a higher rate of procedural success rate in this group. The occurence of non-Q-wave MI was not influenced by use of PES (OR = 0.324, 95% CI 0.0.91-1.160, p = 0.083).

The large registries such as the RESEARCH [15], T-SEARCH [16], and REWARD [17], which lacked routine follow-up angiography, have consistently detected no difference between these two groups in terms of follow-up clinical outcomes. Our results are consistent with all these large registries. In the T-SEARCH registry, there was an inferior crude rate of clinical MACE attributed to the more complex profile in this group [16]. In a subset of patients with complex lesions, no clinical differences were noted between SES and PES, which was in conformity with the mentioned studies [18].

In fact, in many randomised trials, SES has been associated with superior suppression of neointimal hyperplasia compared to PES, resulting in a reduction of in-stent and in-segment late loss. However, this was not always associated with a reduction in binary restenosis, TVR, and MACE, as in the case of REALITY, a large randomised trial [11]. On the other hand, some smaller randomised trials such as ISAR-SMART and SIRTAX have shown the superiority of SES over PES in either angiographic or clinical parameters [8, 19]. A meta-analysis of 16 randomised trials of sirolimus- versus paclitaxel--eluting stents in patients with coronary artery disease indicated the superiority of SES over PES in reducing the risk of reintervention and stent thrombosis [20]; in another meta-analysis, the target lesion revascularisation within 6 months was less frequently performed with SES and angiographic restenosis had lower frequency. However, there were no significant differences in stent thrombosis, mortality, and death/MI [21]. Nevertheless, these analyses included different study populations with variable follow-up durations and endpoint definitions, which may be a limitation in drawing a firm conclusion. The TAXi-LATE trial addressed the long-term (3-year) clinical outcomes of stenting with SES vs. PES. This study supported previous published data pointing to the equivalence of PES and SES in treating coronary artery lesions [22].

In our study, the only predictor for both outcomes of TVR and MACE was reference vessel diameter. The maximal suppression of neointimal hyperplasia is important in small vessels [20, 23], which can accommodate less tissue inside the stent. Our results showed that despite using DES, reference vessel diameter was still a predictor of both outcomes.

Study limitations

There are some limitations in this study of a single heart centre. The patients were not randomly assigned to apply PES or SES. Our result showed that TVR rate was low in both groups. However, this may be due to the lack of routine angiographic follow-up in most patients. Therefore, some patients with medical management who developed restenosis were not identified in this clinical follow-up study. Furthermore, follow-up data were available for 91.1% of participants after the procedure.

Conclusion

Although this study bears the general limitations of non-randomisation and was set up in a single academic centre, the differences between the SES and PES groups were adjusted using multivariate analyses. Our findings demonstrate that both drug-eluting stents have similar clinical outcomes, in hospital and in mid-term follow-up.

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Przebieg hospitalizacji i rokowanie po zabiegach przezskórnej interwencji wieńcowej z wszczepieniem stentów uwalniających sirolimus i paklitaksel

Mohammad Alidoosti[1], Mojtaba Salarifar[1], Seyed E. Kassaian[1], Ali M. Haji Zeinali[1], Ebrahim Nematipoor[1], Mahmood Sheikhfathollahi[2], Hamidreza Poorhosseini[1], Maria Raissi Dehkordi[2], Ali Abbasi[1, 3]

[1] Klinika Kardiologii, Tehran Heart Center, Uniwersytet Medyczny, Teheran, Iran

[2] Klinika Chorób Serca i Naczyń, Tehran Heart Center, Uniwersytet Medyczny, Teheran, Iran

[3] Klinika Epidemiologii, Uniwersyteckie Centrum Medyczne, Groningen, Holandia

Streszczenie

Wstęp: Wprowadzenie stentów powlekanych substancjami antyproliferacyjnymi zrewolucjonizowało leczenie inwazyjne choroby wieńcowej poprzez zmniejszenie częstości epizodów restenozy i potrzeby rewaskularyzacji oraz częstości występowania niekorzystnych zdarzeń sercowych (MACE).

Cel: Ocena przebiegu hospitalizacji i rokowania u chorych poddanych planowanemu zabiegowi przezskórnej interwencji wieńcowej (PCI) z implantacją dwóch różnych typów stentów powlekanych: uwalniających sirolimus (SES) i paklitaksel (PES).

Metody: Grupę badaną stanowiło 1311 kolejnych chorych poddanych zabiegowi PCI z implantacją SES (grupa SES) lub PES (grupa PES) w okresie od marca 2003 do marca 2007 r. Z badania wykluczono chorych z ostrym zawałem serca (MI), który wystąpił w czasie do 48 godz. od zabiegu PCI.

Wyniki: Grupy SES i PES różniły się co do anatomii zmian w tętnicach wieńcowych poddanych PCI. W grupie PES częściej występowały zmiany w zagięciach tętnic i w odcinkach proksymalnych (odpowiednio 15,9 *vs* 7,2%, p = 0,001, oraz 46,4 *vs* 27,1%, p < 0,001), natomiast w grupie SES częściej występowały zmiany w ujściach tętnic i w gałęzi przedniej zstępującej lewej tętnicy wieńcowej (odpowiednio 7,2 *vs* 4%, p = 0,022; oraz 80,2 *vs* 69,1%, p < 0,001). W grupie SES w trakcie hospitalizacji częściej stwierdzano MI bez załamka Q (2,2 *vs* 0,7%, p = 0,039), ale związek pomiędzy typem wszczepionego stentu a wystąpieniem MI bez załamka Q w trakcie hospitalizacji, w analizie wieloczynnikowej, nie był istotny statystycznie (p = 0,083). W trakcie obserwacji odległej (średnio 16,7 ± 7 miesięcy) zmarło 5 chorych w grupie SES i 3 w grupie PES (p = 0,749). Częstość występowania MACE i konieczności ponownej rewaskularyzacji naczynia docelowego (TVR) była podobna w grupie SES i PES (odpowiednio 5,5 *vs* 3,3%, p = 0,138, oraz 2,0 *vs* 1,6%, p = 0,213). W analizie wieloczynnikowej średnica referencyjna naczynia była niezależnym predyktorem TVR (HR 0,170, 95% CL 0,034–0,837, p = 0,029) i wystąpienia MACE (HR 0,333, 95% CL 0,120–0,925, p = 0,035).

Wnioski: W średnioterminowej obserwacji odległej skuteczność kliniczna implantacji SES i PES jest podobna.

Słowa kluczowe: stent uwalniający sirolimus, sten uwalniający paklitaksel, rokowanie

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Adres do korespondencji:

dr n. med. Mohammad Alidoosti, Department of Cardiology, Tehran Heart Center, Tehran University of Medical Sciences, North Kargar Street, Tehran Heart Center, Tehran, 1411713138, Iran, tel./faks: +98 21 880 292 56, e-mail: alidoostitums@gmail.com

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