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ARTYKUŁ ORYGINALNY / *ORIGINAL ARTICLE*

Outcomes of biodegradable polymer sirolimus-eluting PROLIM stent in patients with coronary artery disease. Results of 12-month follow-up of prospective registry

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Abstract

Background: Data from clinical trials suggested that biodegradable-polymer-based drug-eluting stents (DES) might improve long-term clinical outcomes. PROLIM (Balton, Warsaw, Poland) DES is based on a stainless steel platform with a closed cell design releasing sirolimus from biodegradable copolymer (lactic and glycolic acid) in eight weeks.

Aim: In the present study the safety and the efficacy of a PROLIM stent was assessed in patients with de novo coronary lesions in 12-month clinical follow-up.

Methods: It was a single-centre, observational, prospective registry to assess the safety and efficacy of a PROLIM stent implantation in all consecutive patients with de novo coronary artery lesions treated with percutaneous coronary intervention (PCI). The primary study endpoint was a composite safety (cardiac death, non-fatal myocardial infarction), and the second study endpoint was the efficacy of PROLIM implantation-clinically driven target vessel revascularisation (TVR) assessed at 12-month follow-up.

Results: One hundred patients were enrolled into the study and 118 PROLIM stents were implanted. Thirty-two (32%) patients had diabetes, 46 (46%) patients were prior PCI, and 17 (17%) patients had coronary artery bypass grafting. 67% of stented lesions were complex ones (B2/C) and 17% were bifurcations. During the 12-month follow-up primary study endpoints occurred in five (5%) patients. Two (2%) cardiac deaths were reported and three (3%) TVRs were performed, of which one was related to in-PROLIM stent restenosis.

Conclusions: PCI with biodegradable-polymer PROLIM DES seems to be safe and effective in 12-month follow-up. A larger trial is warranted to assess clinical outcomes post PROLIM stent implantation.

Key words: drug-eluting stents, biodegradable polymer, sirolimus

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INTRODUCTION

Drug eluting stent (DES) implantation was shown to present significant superiority over bare metal stent (BMS) implantation [1]. However, the promising results of first-generation DES, in terms of reduced incidence of restenosis, were counterbalanced by increased risk of late and very late stent thrombosis as compared to BMS [2]. Delayed vessel healing was suggested to be responsible for that phenomenon. The first generation of sirolimus-eluting stents (SES) was based on a durable polymer that induced high inflammatory response and peri-strut fibrin deposition, which delayed vessel healing and probably increased the risk of stent thrombosis [3]. To improve the outcomes of SES implantation, biodegradable polymer (BP) stents were designed [4, 5]. Histological, studies presented a decreased inflammatory response to stents coted with BP [6] and initial clinical studies have proven its superi-

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ority over the durable polymer SES [7–9]. Therefore, a new BP coated sirolimus-eluting PROLIM stent was also designed by the company Balton (Warsaw, Poland) [10]. Preclinical observations in the porcine model showed favourable vessel healing post implantation of PROLIM stent [10], hence the question arises whether it translates into improved clinical outcomes. In present study, the safety and the efficacy of PROLIM stent were evaluated in unselected patients with de novo coronary lesions at 12-month clinical follow-up.

METHODS

It was a single-centre, observational, prospective study to assess safety and efficacy of a BP coated sirolimus eluting PROLIM stent in unselected patients with de novo coronary artery lesions and with de novo saphenous graft lesions The patients were enrolled into the study between June 2012 and March 2013. The registry evaluated the outcomes of patients routinely treated in the Upper Silesian Medical Centre, and the use of the stent was based on the operators' choice.

Device description

PROLIM is a balloon expandable stent dedicated for coronary lesions. The stent platform (Flexus, Balton, Poland) is made of a laser-cut 316 L stainless steel tube with strut thickness of 0.115 mm. It has a closed cell design and a metal-to-artery surface ratio of 19%. The PROLIM is covered with a copolymer of lactic and glycolic acid and sirolimus mixture sprayed onto the stent. There is no primer or topcoat layer. The coating degrades entirely within eight weeks [10].

Criteria of enrolment

Inclusion criteria were: age > 18 years, and stable coronary disease or acute coronary syndromes (unstable coronary disease, non ST elevation myocardial infarction [NSTEMI] and ST elevation myocardial infarction [STEMI]). The exclusion criteria were as follows: contraindication to the 12-month dual antiplatelet therapy (DAPT), cardiogenic shock, chronic coronary vessel occlusion, in-stent restenosis, left main disease, and multivessel coronary disease eligible for coronary artery bypass grafting (CABG).

Percutaneous coronary intervention

All patients received aspirin and clopidogrel prior to percutaneous coronary intervention (PCI) and unfractioned heparin to achieve activated clotting time > 300 s. PROLIM stent implantation was made at the operator's discretion according to the European Society of Cardiology guidelines for myocardial revascularisation [11]. The choice of revascularisation strategy was left to the operator. Procedural success was defined as residual stenosis less than 20% and the presence of thrombolysis in myocardial infarction (TIMI) 3, as assessed by angiography.

Patient follow-up and study endpoints

A flow chart of the study is presented in Figure 1. The patient's outcomes were evaluated by clinic visit or by phone contact at 12-month follow-up. If clinically indicated (positive exercise test or recurrent angina) coronary angiography was performed and the angiographic data was recorded at the 12-month follow-up clinical visit. The primary study endpoint was a composite safety (cardiac death, non-fatal myocardial infraction). The second study endpoint was efficacy of PROLIM implantation (clinically indicated target vessel revascularisation [TVR]) during the 12-month follow-up. All deaths were considered as cardiac, unless non-disputed non-cardiac cause of death was present. TVR was defined as any revascularisation within the treated vessel.

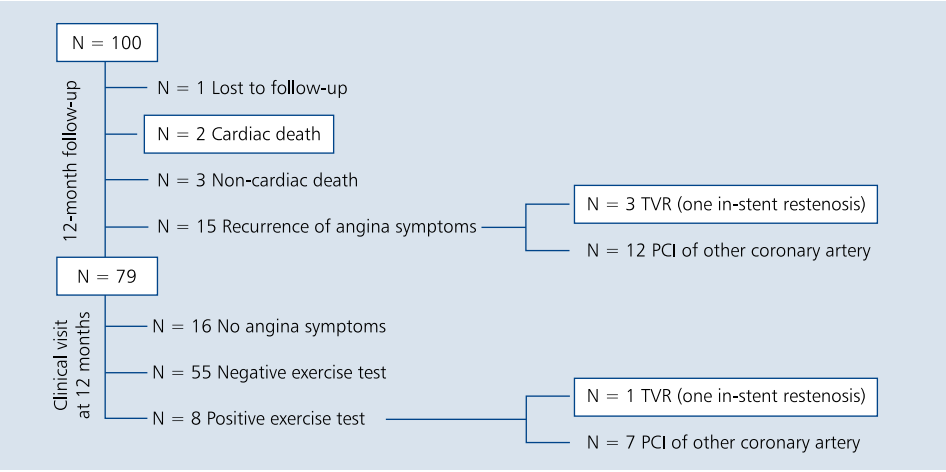

Figure 1. Study flow chart. The figure presents the results of patients' follow-up. Primary study endpoints are presented in boxes; N — number of patients; PCI — percutaneous coronary intervention; TVR — target vessel revascularisation

Quantitative coronary angiography analysis

Quantitative coronary angiography analysis was performed by an independent core laboratory at Krakow Cardiovascular Research Institute (KCRI). The morphology of stented lesion was defined according to the classification proposed by the American College of Cardiology/American Heart Association [12]. Lesion length, minimum lumen diameter, reference vessel diameter, percentage diameter stenosis (%DS), and the coronary flow (TIMI classification) were assessed before and post index procedure.

Statistical analysis

The Kolmogorov-Smirnov test was used to assess the data distribution. Normally distributed values were presented as mean with standard deviation. Non-normally distributed values were presented as median with 25th and 75th percentile (interquartile range [IQR]). The statistical analysis was performed using Medcalc 14.12 (Medcalc software).

RESULTS

Patients' characteristic

The registry included 100 patients with de novo lesions in coronary arteries and with de novo lesions in coronary saphenous grafts, 66% male, mean age 66.08 ± 10.23 years. At presentation 71% of patients had acute coronary syndromes (13% STEMI, 8% NSTEMI, and 50% unstable angina). Thirty-two (32%) patients had diabetes, 46 (46%) patients had history of PCI, and 17 (17%) patients had undergone CABG in the past. The patients' characteristics are presented in Table 1. Details about medical treatment are presented in Table 2. All patients received DAPT at discharge and continued the therapy throughout 12-month follow-up.

Lesion characteristics

Quantitative coronary angiography analysis was available in 98 of 100 lesions treated with PROLIM stent implantation. 91% of stented lesions were located in native coronary arteries, and 9% were located in saphenous vein grafts. 67% of lesions were complex ones (B2/C) and 17% were located on bifurcations. Stented lesions were 15.65 mm (IQR 11.08, 23.22) long with %DS 67.72 ± 17.41. Results of quantitative coronary angiography analysis are summarised in Table 3.

Procedural characteristics

There were 118 PROLIM stents implanted in 100 patients. Mean stent length was 18 mm (IQR 12, 22) and mean diameter was 3.0 mm (IQR 2.5, 3.5). Ninety (90%) patients received one stent, eight (8%) patients received two, and two (2%) patients received three stents. Postdilatation was performed in 14% of patients. An edge dissection occurred in three (3%) patients. Bailout stenting was required in four (4%) patients. Three (3%) lesions had residual stenosis more than 20%, and post procedure TIMI 3 was present in 89% of patients (Table 4).

Table 1. Patients' characteristic (n = 100)

Age [years]	66.08 ± 10.23
Male gender	66 (66%)
Myocardial infarction:	21 (21%)
STEMI	13 (13%)
NSTEMI	8 (8%)
Unstable angina	50 (50%)
Stable coronary disease	29 (29%)
Risk factors:	
Hypertension	75 (75%)
Hyperlipidaemia	50 (50%)
Diabetes mellitus	32 (32%)
Current smoking	37 (37%)
Prior MI	28 (28%)
History of PCI	46 (46%)
History of CABG	17 (17%)
Previous stroke	9 (9%)
Family history of CAD	34 (34%)

STEMI — ST elevation MI, NSTEMI — non ST elevation MI; MI — myocardial infarction; PCI — percutaneous coronary intervention; CABG — coronary artery bypass grafting; CAD — coronary artery disease

Table 2. Patient pharmacotherapy at discharge

Pharmacological therapy	100 patients
Aspirin	100 (100%)
Thienopyridine	100 (100%)
Beta-adrenergic antagonist	76 (76%)
Calcium channel antagonist	55 (55%)
ARB/ACEI	82 (82%)
Statin	95 (95%)
Other lipid lowering therapy	2 (2%)
Oral antidiabetics	26 (26%)
Insulin	12 (12%)

ACE — angiotensin converting enzyme inhibitor; ARB — angiotensin receptor blocker

Patient follow-up and primary study endpoint

The mean follow-up was 11.4 ± 2.4 months. One patient was lost to follow-up. During 12-month follow-up, there were five (5%) deaths, including two (2%) cardiac deaths related to heart failure and three (3%) non-cardiac related to pneumonia, lung cancer, and critical lower limb ischaemia. No definitive in-stent restenosis was diagnosed as assessed by angiography. None of the patients had myocardial infraction. Fifteen (15%) patients had a recurrence of coronary artery dis-

Table 3. Quantitative coronary analysis of lesions at baseline

Lesion location:	
LAD	29 (30%)
CX	37 (38%)
RCA	23 (23%)
Saphenous vein graft	9 (9%)
Lesion length	15.65 (IQR 11.08, 23.22)
RVD [mm]	2.71 ± 0.56
MLD [mm]	0.86 ± 0.55
Diameter stenosis [%]	67.72 ± 17.41
TIMI flow:	
0	13 (13%)
1	3 (3%)
2	23 (23%)
3	59 (60%)
Lesion class:	
A/B1	31 (32%)
B2/C	67 (68%)
Bifurcations	17 (17%)
Thrombus presence	12 (12%)
Severe calcification	2 (2%)

IQR — interquartile range; LAD — left anterior descending artery; CX — circumflex artery; RCA — right coronary artery, RVD — reference vessel diameter; MLD — minimal lumen diameter; TIMI — thrombolysis in myocardial infarction

Table 4. Quantitative coronary analysis of stent implantation results at baseline

Stent length	17.93 (IQR 14.65, 27.52)
Stent diameter	2.70 (IQR 2.39, 3.15)
Predilatation	30 (31%)
Direct stenting	68 (69%)
Postdilatation	14 (14%)
Residual diameter stenosis [%]	5 (IQR 2, 8)
Residual MLD in stent	2.59 ± 0.48
	2.56 (IQR 2.20, 2.92)
Residual dissection:	3 (3%)
Type A	2 (2%)
Type D	1 (1%)
Bailout stenting	4 (4%)
TIMI flow post procedure:	
0	1 (1%)
1	2 (2%)
2	8 (8%)
3	87 (89%)
Thrombus post procedure	1 (1%)

IQR — interquartile range; MLD — minimal lumen diameter; TIMI — thrombolysis in myocardial infarction

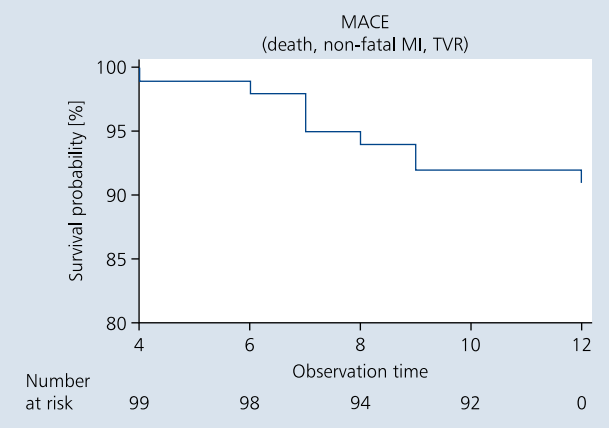

Figure 2. Kaplan-Meier analysis for major adverse cardiac events (MACE). The figure presents the Kaplan-Meier curve of MACE. It included the occurrence of any death, non-fatal myocardial infarction (MI), and any target vessel revascularisation (TVR) within the treated vessel

ease symptoms and were subjected to repeated angiography during the 12-month follow-up. Three (3%) of these patients had TVR. One was related to in-stent restenosis in the treated segment that occurred eight months post procedure. Twelve (12%) had a PCI of another coronary artery; two were related in another segment of the vessel. Summarising, during the 12-month follow-up, primary study endpoints occurred in five (5%) patients, as follows (Fig. 2).

At 12-month clinic visit eight patients had a positive exercise test and were referred for coronary angiography. Due to coronary angiography results, one patient had a TVR because of in-PROLIM stent restenosis, and the other seven had a PCI of another coronary artery at 12-month follow-up.

DISCUSSION

The implantation of durable polymer DES is a standard care of patients with coronary artery lesions. Studies assessing BP-DES presented non-inferiorly to durable polymer DES, with a hope for decreased inflammatory response post stent implantation, and thus with a hope for faster vessel healing [13–16]. Moreover, BP-SES implantation in patients with more severe coronary artery disease was characterised by improved clinical outcomes, as compared to implantation of durable DES [17]. Histological studies presented favourable vessel healing post BP-SES PROLIM stent implantation, which warranted clinical assessment [10]. It was the first study presenting the clinical outcomes of PROLIM stent implantation in patients with de novo coronary lesions. PROLIM stent implantation seemed to be characterised by safety and efficacy at 12-month follow-up.

These results are in line with previous large observational studies of BP-SES implantation. Initial results of the prospective CREATE trial assessing the safety of BP SES EXCEL stent presented that TVR occurred in 4% of patients at 12-month

follow-up, and all TVRs were related to the in-stent restenosis of the EXCEL stent [18]. Moreover, Seth at al. [19] presented that in stent restenosis occurred in one patient at eight-month follow-up post BP-SES implantation. However, the CREATE trial was characterised by very small exclusion criteria, and more complex lesions were stented. Most importantly, the angiography verification was performed at follow-up in the CREATE trial, which was not done in our study [18]. That may lead to underestimation of actual restenosis in PROLIM stents. The observed rate of TVR (5%) in our study was similar to those observed in other large BP-SES studies like the INSPIRE trial (3.9% of TVR) [20] and COMPARE II trial (3.7% of TVR) [16] at 12-month follow-up. Furthermore, the randomised BIOFLOW II trial confirmed promising results of these initial observational studies and presented non-inferiority of BP-SES as compared to everolimus eluting stents [21].

The rate of primary study endpoint (composite of cardiac death, myocardial infarction, and clinically driven TVR) in our study was in line with the COMPARE II trial, in which it occurred in 4.9% of patients at 12-month follow-up [16]. Moreover, in the larger observational INSPRIRE trial, a study of 1000 patients post BP-SES NOBORI stent implantation, a similar primary study endpoint occurred in 4.0% of patients [20]. These promising results of 12-month follow-ups were confirmed in the CREATE trial of 2077 patients followed up for five years post BP-SES EXCEL stent implantation [9].

Similarly to other BP-SES stents, PROLIM stent implantation seemed to present favourable clinical outcomes at 12-month follow-up. Hence, the question arises whether the DAPT may shorten post implantation. As previously shown, BP-SES implantation presented good clinical and angiographic outcomes in patients subjected to six months of DAPT [18, 22]. Initial optical coherence tomography reports showed that BP-SES characterised faster coverage with neointima, as compare to durable SES [8]. The lack of documented stent thrombosis during the study follow-up warrants an optical coherence tomography study to determine whether the BP-SES PROLIM stent presents satisfactory coverage by neointima at six-month follow-up [23].

Limitation of the study

This was a non-randomised prospective trial; hence the lack of a control group is the main limitation of the study. It was a relatively small group of patients, and observations in larger group of patients is needed to confirm the safety of PROLIM stent implantation. The study was based on clinical follow-up, and control coronary angiography was performed only from clinical indications. Thus, some of the PROLIM stent failures might have been missed. Finally, not every operator in the Upper Silesian Medical Centre participated in the study, which extended patient enrolment.

CONCLUSIONS

Percutaneous coronary intervention with biodegradable-polymer PROLIM DES seems to be safe and effective in 12-month follow-up. These promising results warrant a larger trial to assess clinical outcomes post implantation.

Conflict of interest: *none declared*

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Roczna obserwacja pacjentów po implantacji stentu zawierającego biodegradowalny polimer i uwalniającego sirolimus — PROLIM stent

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Streszczenie

Wstęp: Wyniki badań klinicznych sugerują, że implantacja stentów uwalniających lek (DES) zawierających biodegradowalny polimer istotnie poprawia wyniki przezskórnego leczenia pacjentów z chorobą wieńcową. PROLIM (Balton, Warszawa, Polska) jest stentem typu DES zawierającym polimer, który ulega biodegradacji 8 tygodni po implantacji.

Cel: W niniejszym jednoośrodkowym prospektywnym badaniu oceniono wyniki przezskórnego leczenia nowo powstałych zmian w naczyniach wieńcowych za pomocą stentu PROLIM w długoterminowej obserwacji.

Metody: Pierwszorzędowym punktem końcowych badania była łączna ocena bezpieczeństwa implantacji stentu PROLIM (zgon sercowy, zawał serca) oraz skuteczności leczenia nowo powstałych zmian w naczyniach wieńcowych (rewaskularyzacja leczonego naczynia) w 12-miesięcznej obserwacji. Do badania włączono 100 pacjentów, którym implantowano 118 stentów PROLIM.

Wyniki: Spośród badanych 32 (32%) pacjentów chorowało na cukrzycę typu 2, 46 (46%) było poddanych wcześniejszej przezskórnej rewaskularyzacji, a 17 (17%) — wcześniejszej chirurgicznej rewaskularyzacji naczyń wieńcowych. U 67% leczonych stwierdzono zmiany typu B2/C, a 17% dotyczyło bifurkacji. W 12-miesięcznej obserwacji pierwszorzędowy punkt końcowy zaobserwowano u 5 (5%) pacjentów. Dwie (2%) osoby zmarły w przebiegu badania, a u 3 (3%) chorych wykonano ponownie przezskórną angioplastykę leczonego naczynia, z których 1 była wskazana ze względu na restenozę w implantowanym stencie PROLIM.

Wnioski: W obserwacji długoterminowej implantacja stentu PROLIM wydaje się bezpieczna i skuteczna w leczeniu pacjentów z nowo powstałymi zmianami w naczyniach wieńcowych.

Słowa kluczowe: stent typu DES, biodegradowalny polimer, sirolimus

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