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ARTYKUŁ ORYGINALNY / *ORIGINAL ARTICLE*

Self-expanding STENTYS stents in daily routine use

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Abstract

Background: In the era of modern interventional cardiology, implantation of a balloon expandable stent is the finishing touch of almost every coronary angioplasty. However, sometimes we face a clinical situation in which the decision regarding the stent diameter is complicated, especially in the ectatic part of arteries, in situations when the artery lumen is obscured with the thrombus, or when the reference diameter of the proximal and distal part of the lesion vary greatly. That is why the idea of a self-apposing stent similar to the one used in peripheral vascular interventions was adopted into cardiology.

Aim: The aim of this study was to present a single-centre registry of STENTYS® stent implantation in 40 selected patients with acute coronary syndromes (ACS) or with stable angina (coronary artery disease [CAD]) treated with this self-expandable stent.

Methods and Results: The device was successfully implanted in all patients. During in-hospital observation and 30-day follow-up there were two cases of death, but none of the patients had acute stent thrombosis or ACS ST elevation myocardial infarction. In one case ACS type 4b was diagnosed. In all patients the stent was delivered in the target lesion. In two cases the procedure was performed in patients with multivessel CAD extending into the left main stem in a state of cardiogenic shock. These patients died immediately after the procedure. There were two procedure complications: in one case dissection after post dilatation occurred distally to the stent, and in one patient the calcified proximal part of the left anterior descending artery was dissected with system passage. Thirty-eight patients survived the 12-month follow-up period, and three (7.8%) patients underwent repeated target-lesion revascularisation.

Conclusions: In the presented single-centre registry the STENTYS® stent was used with a high delivery and procedural success rate. Satisfactory clinical long-term outcome both in stable patients and ACS patients with a repeated revascularisation ratio of 7.8% was observed. The stent design allowed successful treatment of bifurcation lesions.

Key words: coronary artery angioplasty, coronary ectasia, bifurcation lesion, self-expanding stent

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INTRODUCTION

Percutaneous coronary intervention (PCI) with balloon angioplasty and stent implantation is considered as the optimal approach for the treatment of patients with coronary artery disease (CAD), especially those with acute coronary syndrome (ACS) [1]. However, in some groups of patients the results of angioplasty even with stent implantation are characterised by lower procedural success and worse clinical outcomes [2]. These situations include patients with ACS when the lumen of the artery is obscured due to thrombus formation or vessel contraction, patients with lesions located in the vein graft, or those with atypical coronary anatomy [3]. Therefore, there is a risk of implantation of an undersized stent, which may lead to stent malapposition, which is a primary predictor of stent thrombosis and restenosis [4]. On the other hand, stent oversizing may also be dangerous, causing vessel wall dissection, perforation, and distal embolisation with no-reflow effect. Both under- and oversizing of the implanted stent may lead to increased risk of adverse clinical events. Intravascular ultrasound (IVUS) or optical coherence tomography (OCT)-guided angioplasty can easily overcame the mentioned problems [5]. However, this procedure in ACS patients may not be covered by the national health system in selected countries (e.g. in Poland). Therefore, it may be rational to use a stent that has the ability to self-expand over time [6]. Interventions in coronary bifurcations have significantly higher rates of restenosis. PCI of the complex bifurcation lesion not only increases the risk of restenosis but also may increase the risk of stent thrombosis when some of the stent struts are left unopposed. To overcome these limitations the STENTYS® stent has been introduced [7].

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The delivery system of this stent is similar to those used in peripheral vascular interventions. STENTYS® is characterised by a constant outward radial force and it continues to expand over time, so the stent is able to adapt itself to the varying proximal and distal diameters of the artery. STENTYS® is made of nitinol (nickel–titanium alloy) and is deployed by the withdrawal of a retractable sheath. The stent may be maximally expanded up to 7.0 mm diameter. The STENTYS® stent has disconnectable interconnections between struts, which can be opened with balloon inflation to create side branch (SB) access. After the struts open outward the force of the stent is directed towards the carina, so a final "kissing balloon" technique is not mandatory [8–10]. In the present study we were interested in the technical aspects and outcomes of STENTYS® stent implantation in a non-randomised group of patients selected for the procedure by a physician performing angioplasty.

The aim of this study was to present a single-centre registry of the STENTYS® stent implantation in 40 selected patients.

METHODS

This was a single-centre, non-randomised retrospective registry study of 40 patients with ACS or with stable angina (CAD) treated with a self-apposing STENTYS® stent hospitalised between the beginning of 2013 and March of 2015. Metabolic disorders like diabetes mellitus or hypercholesterolaemia were diagnosed in 38 patients (diabetes mellitus type 2 in 10 patients, hypercholesterolaemia in 28 patients). Lipid lowering therapy was administered in 35 patients including rosuvastatin in 20 patients (mean dose 10 mg), atorvastatin in eight patients (mean dose of 20 mg daily), and in seven cases simvastatin in a dose of 10 mg daily. Ten patients had diagnosed diabetes mellitus, and four of them were on insulin therapy. Mean values of glycated haemoglobin (HbA1c) indicated optimal glucose lowering therapy in those patients (Table 1). Beta-blocker therapy was administered in 37 patients, angiotensin converting enzyme inhibitors in 33 patients, angiotensin receptor blockers in nine patients, diuretics in 21 patients, and calcium channel blockers in 17 patients.

The use of a STENTYS® stent was left to the discretion of the interventional cardiologist performing the procedure. If not treated before the procedure, each patient received a loading dose of antiplatelet therapy: 300 mg of acetylsalicylic acid (ASA), 600 mg clopidogrel, and a heparin bolus of 100 IU/kg IV. The bolus of glycoprotein IIb/IIIa inhibitor was administered in patients with ACS if needed. Use of bivalirudin was accepted. After the procedure, patients received ASA (75 mg/day) and clopidogrel (75 mg/day for a month or for 12 months after the procedure — ST elevation myocardial infarction [STEMI], non-ST elevation myocardial infarction [NSTEMI] and patients with drug eluting stent [DES]). Predilatation of target lesion was performed in all cases. In patients with ACS thrombus aspiration was left to the discretion of the performing physician. In the case of bifurcation lesion with SB ostium covered by stent, stent strut disconnection was performed if the diameter of the SB was > 2.5 mm with thrombolysis in myocardial infarction (TIMI) flow < 3, with proximal stenosis greater than 50% by quantitative coronary analysis (QCA). Stent post-dilatation was performed in the case of residual stenosis more than 30% in QCA or if incomplete stent apposition was found in IVUS. Stents available for use were: bare-metal stent (BMS) with a nominal strut width of 68 μm, and DES with polysulphone polymer eluting paclitaxel. Stent lengths used were 22 mm and 27 mm with a diameter suitable for vessels with a reference vessel diameter between 2.5 mm and 4.5 mm.

The authors declare that the study complies with the Declaration of Helsinki. The research protocol was approved by the locally appointed Ethics Committee, and informed consent of the subjects was obtained.

Angiographic and IVUS assessment

During the procedure the lesion length, reference vessel diameter in 5-mm segments proximal (PRD) and distal (DRD) to the culprit lesion, minimal lumen diameter (MLD), and stenosis assessment was performed with the use of QCA software built into a Siemens Artis Zee system. From these measurements the stenosis diameter was calculated.

Intravascular ultrasound images were acquired with a Boston I-lab system and Opticross transducer by motorised pull-back at a constant speed of 0.5 mm/s after intracoronary administration of 0.2 mg nitroglycerin. Reference segments of the index artery were at the points of 5 mm proximal and distal to the target lesion. Then the reference external elastic membrane (EEM) area was measured with subsequent measurements of the reference lumen area (RLA). RLAs were measured in segments 5 mm proximal (pRLA) and distal (dRLA) to the target lesion. In the target lesion, in the narrowest part, the minimal lumen area (MLA) and EEM were measured. The percentage of area of stenosis was calculated as (RLA − MLA)/RLA × 100 (%). The lesion length was measured using the motorised pullback device.

Follow-up timelines

Clinical data was collected and assessed before and after the procedure, at discharge, and 6 and 12 months after the procedure. The primary endpoint for the study was major advance cardiac event (MACE), defined as: death, recurrent myocardial infarction (MI), stent thrombosis, urgent target vessel revascularisation (TVR), and clinically driven target lesion revascularisation (TLR).

Definitions

Death of the patient was considered cardiac unless a non-cardiac cause was identified. MI was diagnosed with the third universal definition of MI [11].

Table1. Demographic and clinical data of patients

Age [years]	61.7 ± 11.2
Female	15 (38%)
Diabetes mellitus	10 (25%)
Mean glucose level [mmol/L]	6.2 ± 1.8
HbA1c [%]	6.8 ± 0.3
Hypertension	29 (72%)
Mean BP systolic values [mm Hg]	130 ± 21
Mean BP diastolic values [mm Hg]	77 ± 9
Smoker (current)	8 (20%)
Body mass index [kg/m^2]	27.3 ± 9.7
Previous myocardial infarction	11 (27%)
Ejection fraction (%) (estimated by TTE)	51 ± 11
Hypercholesterolaemia	28 (70%)
Mean total cholesterol [mg/dL]	176 ± 45
Mean LDL [mg/dL]	94 ± 33
Mean HDL [mg/dL]	46 ± 12
Chronic kidney disease (GFR < 60)	3 (7.5%)
Mean eGFR (MDRD mL/min/1.73 m^2)	79 ± 19
Total acute coronary syndrome	29 (72%)
NSTEMI	11 (27.5%)
STEMI	18 (45%)
Stable CAD	11 (27.5%)
Prior PCI	13 (32%)
Prior CABG	6 (15%)

Data are presented as mean ± standard deviation or number and percentage (in brackets); CABG — coronary artery bypass graft; CAD — coronary artery disease; BP — blood pressure; eGFR — estimated glomerular filtration rate; HbA1c — glycated haemoglobin; HDL — high-density lipoprotein; LDL — low-density lipoprotein; NSTEMI — acute coronary syndrome without ST segment elevation myocardial infarction; PCI — percutaneous coronary intervention; STEMI — acute coronary syndrome with ST segment elevation; TTE — transthoracic echocardiography

Table 2. Angiographic findings, target lesion characteristic, and technical data of the procedures

Multivessel disease	27 (67.5%)
Mean bifurcation angulation [degrees]	59 ± 23
Diameter stenosis [%]	89 ± 14 (min 75 – max 100%)
Mean lesion length [mm]	20.7 ± 6.2
Technical success	40 (100%)
Device success	37 (96.1%)
Angiographic success	39 (98.9%)
Procedural success	37 (96.1%)
Total mean procedure time [min]	57.8 ± 36.2
Intra-aortic balloon pump	2 (1.9%)
Thrombus aspiration	19 (47.5%)
Post dilatation performed	24 (60%)
Total number of stents used/stent per patient ratio	48/1.2
Target lesion additional stent	6 (15%)
Side branch stenting	1 (2.5%)
Radial access	37 (92%)
Primary femoral access	3 (8%)
Conversion from radial to femoral access	2 (5%)
Contrast dose [mL]	165 ± 29
Radiation dose [mGy]	749 ± 95

Data are presented as mean ± standard deviation or number and percentage (in brackets)

Target vessel revascularisation was defined as a repeated revascularisation (PCI or coronary artery bypass grafting [CABG]) of any segment in the target artery. TLR was defined as repeat PCI because of restenosis within the stent or within the 5-mm segments of the index artery proximal or distal to the stent. Stent thrombosis was defined as in the Academic Research Consortium definition.

Technical success was defined as the ability to cross with the device and deploy the stent at the target lesion.

Angiographic success was defined when TIMI flow 3 in the index artery was achieved with < 20% of the residual stenosis in the target lesion.

Procedural success was defined as technical and angiographic success in the absence of MACE at hospital discharge.

Clinical vs. non-clinically driven TLR was defined as follows: TLR was defined as clinically-driven if the patient had a target lesion diameter stenosis ≥ 50% by QCA and clinical symptoms of angina pectoris or proven ischaemia with: ischaemic changes in rest electrocardiogram (ECG) or in ECG exercise test, or in single-photon emission computed tomography or stress echocardiography related to the index vessel lesion. In-stent restenosis was defined as the presentation of > 50% diameter stenosis in the stented segment of the target artery in angiogram.

Continuous variables are presented as means ± standard deviations, while categorical variables are presented as counts and percentages.

RESULTS

A total of 40 patients with clinical evidence of myocardial ischaemia and de novo coronary lesions were enrolled, including: 18 patients with ACS-STEMI, 11 patients with ACS-NSTEMI, and 11 patients with elective PCI in CAD. Clinical characteristics of the patients and demographics data are displayed in Table 1. Patients were mostly middle-aged (61.7 years), male (62%), and with multiple risk factors for ischaemic heart disease. The majority of patients had disease affecting two or three vessels (67.5%). Target lesions were

mostly in type B or C lesions apart from three cases with type A lesions. Table 2 summarises lesion characteristics at the baseline.

A total of 48 stents were used, including 45 STENTYS® stents (32 BMS and 13 DES). Post-dilatation of the culprit lesion using a noncompliant balloon sized to the vessel reference diameter was performed in 24 cases. Simultaneous kissing balloon technique was performed in 13 patients, and in one patient the proximal part of SB was stented because of significant stenosis. Thrombus aspiration was performed in 19 (47.5%) patients: 12 with ACS-STEMI and 7 in ACS-NSTEMI. Seventeen patients received glycoprotein IIb/IIIa inhibitors (integrillin 12 patients, abciximab 5 patients); despite the fact that thrombus aspiration was performed two patient did not received glycoprotein IIb/IIIa therapy due to increased risk of bleeding (medical history of gastrointestinal bleeding within two months prior to admission). Five patients received more than one STENTYS® stent because of insufficient lesion coverage (four cases) and one because of proximal dissection to the previously implanted stent. In three patients an additional, DES balloon expandable stent was used. The second stent was placed to treat a second lesion revealed distally to the culprit lesion in one patient, and in one patient SB was stented. Finally, in one patient a STENTYS® stent and one additional, overlapping conventional DES stent were implanted in the left anterior descending artery (LAD). In this patient, after reopening of the infarct artery, a STENTYS® stent was implanted. IVUS study demonstrated incomplete stent apposition in the middle part of the lesion; after post dilatation a linear vessel dissection occurred. An entry point (as proven by IVUS scan) was located within the middle part of the lesion under the stent. To treat the dissection a partially overlapping balloon expandable DES stent was placed with TIMI 3 flow. Final TIMI 3 flow after stent implantation was achieved in all patients but one. In that case there was an angiographic finding of slow flow effect. After intracoronary administration of 100 μg of adenosine with glycoprotein (GP) IIb/IIIa inhibitors administration the TIMI grade score increased to 3. Eight cases of ectasia in target vessel were revealed; in those patients proper stent apposition was confirmed with IVUS (Figs. 1, 2). Amongst patients with bifurcations according to the Medina classification [12], 11 (22.5%) patients had disease affecting the SB (true bifurcations), and three (7.5%) patients had disease affecting all three arms (Medina 1.1.1). In all cases SB ostium remained wide open after MB stent implantation. One lesion was trifurcation including the left main artery (LM/LAD), circumflex artery (Cx), and obtuse marginal (OM).

Device success was achieved in all cases. The overall procedural success rate was high at 87.5% (37/40 patients) with no stent thrombosis. Two patients died immediately after PCI procedure. Those were patients with NSTEMI in a state of cardiogenic shock before the procedure was started, with three-vessel CAD and left main stem (LMS) stenosis. These patients were disqualified from CABG treatment by the consulting cardiac surgeon. During PCI procedure the operator was not able to cross the strongly calcified lesions with a balloon expandable stent system even after predilatation with noncompliant balloons (4.0 × 15–20 atm). Therefore, a decision on STENTYS® stent use was made. After STENTYS® stent delivery into the target area, in one case trifurcation LM/LAD/Cx/intermediate (IM) artery a catheter-induced spiral dissection in LM/LAD occurred with closing of both Cx and IM arteries. Both Cx and IM ostia were then reopened followed by additional balloon expandable DES implantation into the dominant Cx with TIMI 3 flow restoration in both branches. STENTYS® stent was deployed in LM/LAD with TIMI 3 flow. Unfortunately, the patient died immediately after PCI in a state of cardiogenic shock with electromechanical dissociation. In the second case (LM-Cx/LAD bifurcation, lesion protruding into Cx) the patient suffered from sudden cardiac arrest (asystole) during coronarography. After resuscitation PCI of LM and LAD ostium was performed with subsequent implantation of a STENTYS® stent in the direction of the LM/Cx followed by opening of the struts into the LAD. During the PCI procedure a second cardiac arrest occurred with asystole present in ECG. The procedure was finished with support of a LUCAS system, but patient died immediately after the procedure. The patient with slow flow described above counted as the third patient who did not achieve procedural success. In this patient, due to troponin level rise, NSTEMI type 4 was diagnosed. Table 3 describes the outcome and technical data of the PCI procedures.

During initial procedure IVUS assessment was performed in 38 patients. Detailed data of IVUS and QCA examination are presented in Table 3.

Long-term clinical and angiographic results

Late follow-up at 12 months was available for all 38 patients. No death or stent thrombosis was reported at long-term follow up. Twenty-four patients were free of symptoms with negative results of ECG exercise test performed six and 12 months after the procedure and therefore were not scheduled for repeated coronary angiography. Table 4 shows the in-hospital and follow-up data of primary endpoint in the studied population.

Angiographic and IVUS follow-up was available for 14 patients, including 11 patients hospitalised because of second stage of previously planned PCI and three patients hospitalised because of ischaemic symptoms or positive results of ECG exercise test. In three (7.8%) patients repeated TVR due to restenosis was needed. During the index procedure those patients had implanted BMS STENTYS® stent, therefore during the second procedure they underwent clinically-driven TLR. One patient was admitted two months after index hospitalisation, with symptoms of unstable angina pectoris and ST segment depression in resting ECG with 40% restenosis

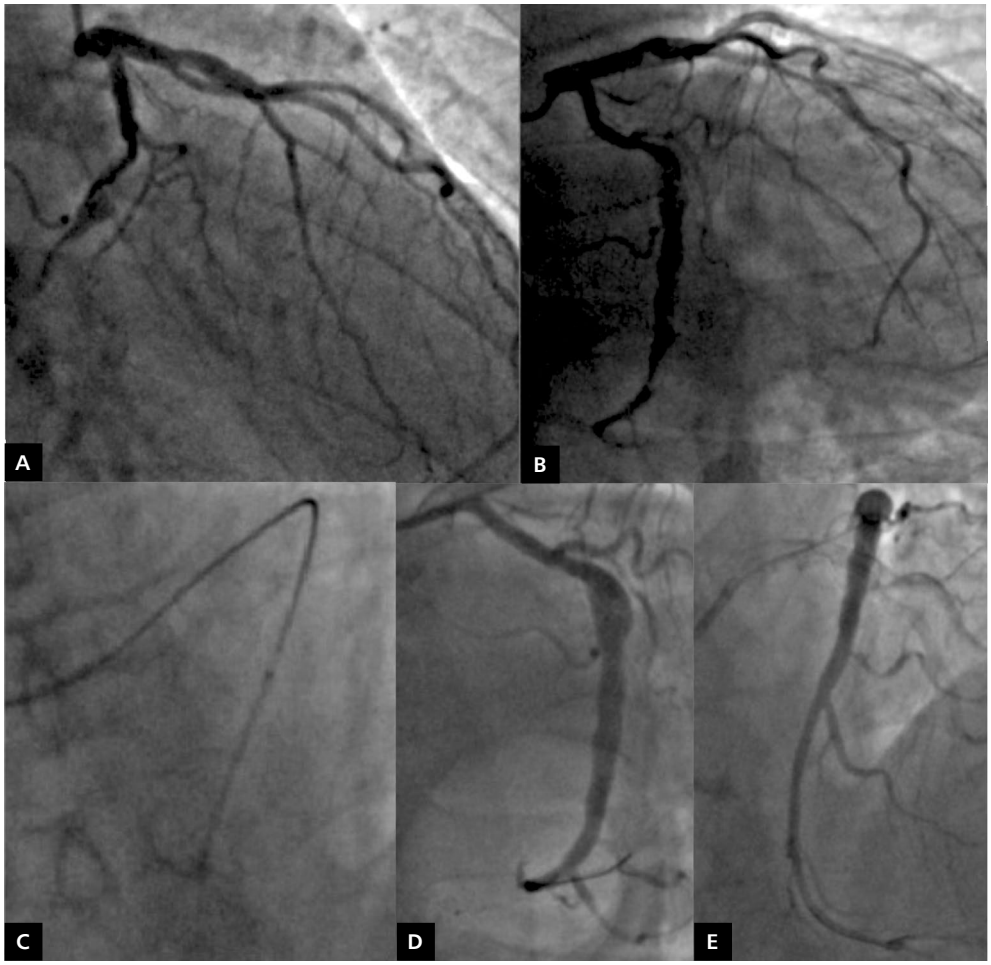

Figure 1. Example of STENTYS® stent implantation in patient with acute coronary syndrome (STEMI ACS); **A.** Acute occlusions of large and ectatic circumflex artery with spontaneous recanalisation (**B**); **C.** STENTYS® stent deployment; **D, E.** Post-implantation images

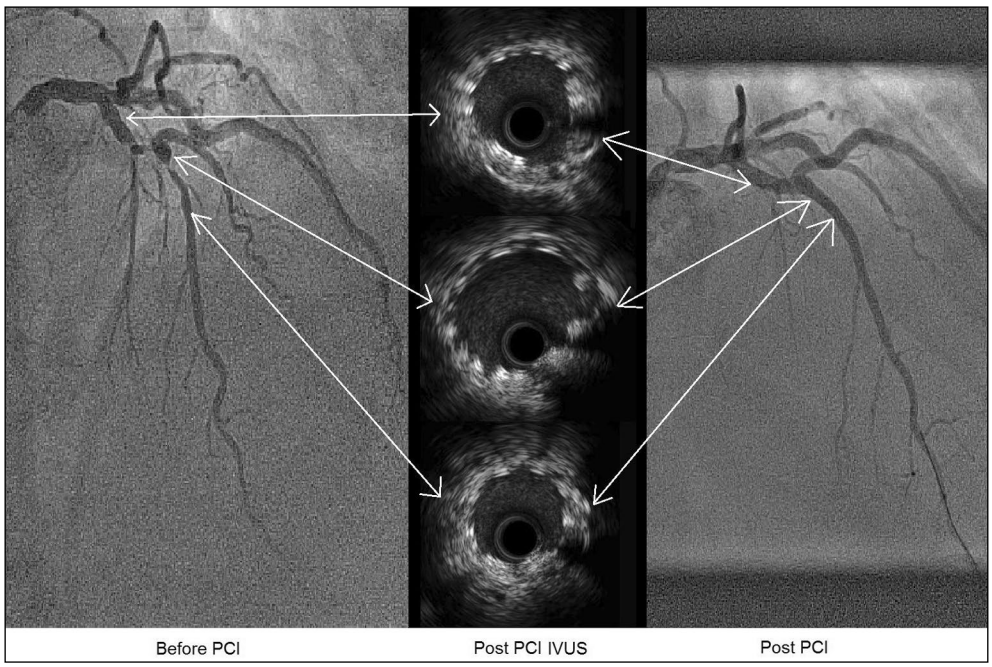

Figure 2. STENTYS® stent implantation with intravascular ultrasound (IVUS) images recorded after stent deployment; PCI — percutaneous coronary intervention

Table 3. Quantitative coronary analysis and intravascular ultrasound (IVUS) parameters in studied patients

	Pre PCI			Post PCI		
	Mean	Median	IQR	Mean	Median	IQR
PRD 5 [mm]	3.3	3.3	0.2	3.4	3.3	0.3
MLD	0.8	0.9	0.5	3.1	3.1	0.2
DRD 5 [mm]	2.3	2.2	0.8	2.7	2.5	0.7
IVUS						
pRLA [mm^2]	7.7	7.8	2.1	7.9	7.9	1.9
dRLA [mm^2]	6.4	6.5	1.2	6.5	6.7	1.1
MLA [mm^2]	2.8	2.9	1.5	5.9	5.4	1.8

PCI — percutaneous coronary intervention; IQR — interquartile range; PRD — mean reference vessel diameter in segment 5 mm proximal to the target lesion; MLD — minimal lumen diameter; DRD — mean reference vessel diameter in segment 5 mm distal to the target lesion; pRLA — reference vessel area in segment 5 mm proximal to the target lesion; dRLA – reference vessel area in segment 5 mm distal to the target lesion; MLA — minimal lumen area

in previously implanted stent in LM/LAD. That patient was treated with a drug-eluting balloon and was free of symptoms during the next 10 months. The second patient (index lesion located in second marginal branch) was admitted three months after procedure due to positive result of ECG exercise test (Bruce protocol, 8 Mets with 2.5 mm ST segment depression in V4–V6 leads). During second angiography there was a 70% in-segment restenosis with the lesion located at the distal edge of a previously implanted 2.5/30 × 27 mm STENTYS® stent. Restenosis was treated with implantation of balloon expandable DES stent 3.0 × 12 mm. The patient was symptom free after nine months of follow-up with negative result of ECG exercise test at 12 months. A third patient, also with positive ECG test (Bruce protocol, 6 Mets with 2.0 mm ST segment depression in I, aVL and V5–V6 leads), hospitalised four months after index PCI, had in-stent restenosis of 60% assessed by QCA. This patient, during repeated PCI with a drug-eluting balloon, experienced an NSTEMI (type 4a) related to closure of marginal branch ostium (reference SB diameter < 2 mm) covered with a previously implanted STENTYS® stent. Among the remaining 11 patients who underwent repeated coronary angiography for the next stage of PCI, there were no late stent thrombosis or restenosis as assessed with QCA and IVUS. The second angiography was usually scheduled from 40 to 50 days (44 ± 8 days) after index procedure. During second angiography IVUS was performed in all patients. Paired QCA and IVUS results of those patients showed significant increase of MLD (post PCI) as compared to pre-procedural MLD. There was a progressive increase in post-procedure MLD and in 5-mm segments of artery proximal and distal to the implanted stent in follow-up QCA measurement; however, the differences were not statistically significant. Detailed results of QCA and IVUS measurements in patients with follow-up angiography are shown in Table 5. MLA, proximal and distal lumen areas showed a trend to increase over time, but the differences were not statistically significant. In follow-up IVUS stent malapposition was not observed nor incomplete lesion coverage.

DISSCUSSION

The main finding of this study is that the STENTYS® stent can be used with a high delivery and procedural success rate. This stent can be used with satisfactory procedural outcome in patients with ACS and stable angina pectoris, especially in patients with atypical coronary anatomy or with coronary bifurcation lesions. We achieved a 100% technical success rate, which is high compared to traditional balloon expandable stents [9–11]. However, the procedures were not free of complications. The use of excessive force in one patient caused a serious dissection of LMS. It should be stated that despite the different platform construction, which eliminated the risk of stent migration during lesion crossing, the use of the STENTYS® stent with high forces in highly calcified lesions may lead to vessel dissection. The STENTYS® stent is not a widely used device. In our site, out of 1360 PCIs only 45 used this stent, i.e. this type of stent counted for 3.3% of procedures. Despite its novel design the implantation process varies from balloon expandable stents. Therefore, it is preferred mainly by experienced operators. Moreover, not every kind of lesion requires a STENTYS® stent. In general practice it is used in ectatic arteries, saphenous grafts, and in bifurcation lesions. The second issue is the cost–effectiveness of the procedure. This stent costs twice as much as the more commonly used DES balloon expandable stent, but implantation of a self-expandable stent is reimbursed in the same manner as regular stent, so the use of STENTYS® is restricted to selected patients.

The presented study is not the first publication describing usage of this stent in Poland. In the PubMed database there are only two (out of 20 found) registered publications regarding STENTYS® from our country. In 2014 Smolka et al. [13] described the results of a pilot registry of LMS stenting

Table 4. Procedure characteristics in the studied group of patients with MACE presentation and number of stents used

Patient	Diagnosis	Bifurcation/ /Medina	Lesion type	Aspiration/ /GP IIb/IIIa	Post-dilatation, struts opening	MACE	STENTYS stent type	Other stents used
1	NSTEMI	1.1.1	Ostial		PD/SO/kissing	Death	DES	
2	NSTEMI	1.1.1	Ostial		PD/SO/kissing	Death	DES	
3	NSTEMI	1.1.1	Ostial	ASP	PD/SO/stent/kissing		BMS	1 BES (DES)
4	STEMI	1.1.0	Ectasia	ASP/ABX			BMS	
5	NSTEMI	1.1.0	Ostial		PD/SO/kissing		DES	
6	STEMI	1.1.0					DES	
7	CAD	1.1.0	Ostial				BMS	
8	NSTEMI	1.1.0	Ostial		PD/SO/kissing		DES	
9	STEMI	1.1.0		ASP/INT	PD		BMS	
10	CAD	1.1.0	Ectasia				BMS	
11	STEMI	1.1.0		ASP/INT			DES	1 BES (DES)
12	NSTEMI	1.1.0	Ostial	ASP/INT	PD/SO/kissing		BMS	
13	CAD	1.1.0				Restenosis/TLR	BMS	
14	STEMI	1.1.0	Ectasia	ASP/ABX			BMS	
15	NSTEMI	0.1.1		ASP/INT	PD/SO/kissing		DES	
16	STEMI	0.1.1			PD/SO/kissing		BMS	
17	CAD	0.1.1	CTO		PD/SO/kissing		DES	
18	STEMI	1.0.1		ASP/INT	PD/SO/kissing		BMS	
19	STEMI	1.0.1		ASP/ABX	PD/SO/kissing		BMS	
20	NSTEMI	0.1.0	Ectasia	ASP			BMS	
21	STEMI	0.1.0			PD		DES	
22	STEMI	1.0.0			PD		2 BMS	
23	NSTEMI	1.0.0	Ectasia			Restenosis/ACS UA/TLR	BMS	
24	CAD	1.0.0			PD		BMS	
25	CAD	0.0.1			PD/SO/kissing		DES	
26	STEMI	0.0.1		ASP/INT	PD/SO/kissing		DES	
27	CAD					Slow flow/ACS type 4	BMS	
28	STEMI			ASP/ABX			2 BMS	
29	STEMI			ASP/INT	PD		BMS	
30	STEMI			ASP/INT	PD		BMS	
31	CAD		Ectasia				2 BMS	
32	CAD		CTO				DES	
33	STEMI			ASP/INT	PD	Dissection	BMS	1 BES (DES)
34	NSTEMI			ASP/INT		Restenosis/TLR	BMS	
35	STEMI						BMS	
36	CAD		Ectasia		PD		BMS	
37	STEMI			ASP/ABX	PD		2 BMS	
38	NSTEMI		Ectasia	ASP/INT	PD		BMS	
39	CAD		CTO				2 DES	
40	STEMI			ASP/INT	PD		BMS	

ABX — abciximab infusion; ACS – acute coronary syndrome; ASP — thrombus aspiration; BES — balloon expandable stent implantation; Bifurcation/Medina — Medina classification of bifurcation lesion; BMS — bare metal stent; CAD — stable coronary artery disease; CTO — chronic total occlusion; DES — drug eluting stent; GP IIb/IIIa — glycoprotein IIb/IIIa inhibitor; INT — integrillin infusion; Kissing — kissing balloon technique; MACE — major adverse cardiac events; NSTEMI — acute coronary syndrome without ST segment elevation; PD — post dilatation; SO — struts opening; STEMI — acute coronary syndrome with ST segment elevation; TLR — target lesion revascularisation; UA — unstable angina

Table 5. Quantitative coronary analysis and intravascular ultrasound (IVUS) parameters of 14 paired patients who underwent repeated angiography

	Pre PCI			Post PCI			Follow up		
	Mean	Median	IQR	Mean	Median	IQR	Mean	Median	IQR
PRD 5 [mm]	3.5	3.5	0.2	3.6	3.6	0.2	3.6	3.6	0.2
MLD	0.8*	0.9	0.7	3.2**	3.1	0.5	3.1**	3.1	0.5
DRD 5 [mm]	2.8	2.8	0.6	2.9	2.9	0.8	2.9	2.9	0.6
IVUS									
pRLA [mm^2]	7.8	7.6	1.3	7.9	7.8	1.4	8.1	8	2
dRLA [mm^2]	6.5	6.5	0.9	6.6	6.7	0.7	7.5	7.2	2.1
MLA [mm^2]	2.8*	2.9	0.8	5.9**	5.3	1.9	6.7**	5.5	2.4

*Pre PCI vs. post PCI and follow-up: $p < 0.01$; **Post PCI vs. follow-up: $p = NS$; PCI — percutaneous coronary intervention; IQR — interquartile range; PRD — mean reference vessel diameter in segment 5 mm proximal to the target lesion; MLD — minimal lumen diameter; DRD — mean reference vessel diameter in segment 5 mm distal to the target lesion; pRLA — reference vessel area in segment 5 mm proximal to the target lesion; dRLA – reference vessel area in segment 5 mm distal to the target lesion; MLA — minimal lumen area

in 24 patients with drug-eluting version of the STENTYS® stent, with satisfactory results. In our study LMS was stented in eight patients with similar technical success; however, as described in the text two patients died because of cardiogenic shock, and in one patient restenosis occurred in the BMS stent. A second study by Mielczarek et al. [14] described successful percutaneous angioplasty of the pulmonary vein with a self-apposing stent. To our knowledge, in the presented manuscript we describe the largest cohort of patients who received self-apposing STENTYS® stents documented in Poland.

Incomplete stent apposition related to underestimation of artery size is one of the main factors contributing to early stent thrombosis. In our study stent thrombosis was not reported in patients with ACS nor in patients with stable CAD. The Apposition II study proved that in patients with a ACS STEMI implantation of self-expandable scaffold was associated with significantly better strut apposition as compared to balloon expandable stents [10]. Therefore, this should be considered as one of the major advantages of the STENTYS® stent. In our study incomplete stent apposition was demonstrated with IVUS only in one patient with ACS. This issue was resolved with high-pressure post-dilatation. Previous studies based on OCT and IVUS assessment confirmed the occurrence of significant epicardial vasoconstriction in the acute phase of ACS. These studies proved that stent under-sizing is a viable problem that needs solution [5]. The STENTYS® stent has the unique ability to increase its diameter and volume after the implantation. The continuous outward force of a self-expandable stent also prevents elastic recoil of the plaque. In our study IVUS examination performed in selected patients at an average time of one and half months after index PCI showed a small increase in MLD and also an increase in the diameter of adjacent artery segments. The most common presentation by patients in our study was bifurcation lesion. Despite many years of research, there is an ongoing debate regarding the approach to bifurcation lesions [11]. These type of lesions need to be treated with PCI in over 20% of patients referred for percutaneous transluminal coronary angioplasty. PCI of bifurcation is associated with lower procedural success and worse clinical outcomes [15]. The recommended strategy favours stenting of the main branch with balloon dilatation of the SB. This strategy, however, in up to 15% of patients may lead to SB ostium stenosis with TIMI flow < 3 with subsequent periprocedural infarction. In the NIRVANA study SB occlusion during PCI of bifurcation lesions caused periprocedural MI in 40% of patients [16]. The differences in STENTYS® stent design make possible to disconnect the struts with complete carina coverage and creation of easy access to the SB ostium. In our study the majority of patients (65%) had bifurcation lesion; however, we were forced to stent the SB in just one case of patient with post-balloon inflation stenosis > 80% extending into the first diagonal branch for 15 mm. Several large trials such as the CADILLAC [17], CACTUS [18] have proven that in a third of cases of stenting of bifurcation lesions a two-stent approach is necessary to avoid the loss of the SB. In our study a two-stent strategy was used only once, so these data may indicate on the potential benefits of the use of the STENTYS® stent in bifurcation lesions. Despite the fact that the implantation technique of the STENTYS® stent version used in this study needs more care and attention than with balloon expandable stents, only short training was needed and it was possible to implant the device in the desired location in each case. Since, before release, the stent is covered under the retractable sheet, it is almost impossible to lose it when passing the lesion, even calcified ones. However, excessive forces used when crossing the lesion may cause a dissection.

Limitations of the study

The main limitation of the study is the limited number of patients included. It was non-randomised retrospective study.

We did not perform direct comparison with balloon expandable stents. The study group was heterogeneous, including patients with ACS and those with stable CAD, so some mechanisms of observed MACE were different e.g. cardiogenic shock leading to death compared to in-stent restenosis in follow-up. These observations made statistical analysis pointless and direct comparison of patients with MACE to those with event-free survival was abandoned.

CONCLUSIONS

In the presented single-centre registry STENTYS® stents were used with a high delivery and procedural success rate. Satisfactory clinical long-term outcome both in stable patients and ACS-patients with the TVR ratio of 7.8% was observed. Then stent design allowed successful treatment of bifurcation lesions.

Conflict of interest: *none declared*

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Stenty samorozprężalne STENTYS w codziennej praktyce kardiologa interwencyjnego

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Streszczenie

Wstęp: Zabieg angioplastyki naczyń wieńcowych (PCI) jest uznaną metodą leczenia choroby wieńcowej. Jednak u niektórych pacjentów ze złożoną morfologią naczyń wieńcowych jest niezmiernie trudno oszacować referencyjną średnicę naczynia. Dlatego też wydaje się, że użycie stentów samorozprężalnych, które adaptują się do średnicy naczynia, może być korzystne.

Cel: Celem pracy była ocena zabiegów PCI wykonanych z wykorzystaniem stentu samorozprężalnego STENTYS®.

Metody i Wyniki: Grupę badaną stanowiło 40 pacjentów z chorobą wieńcową stabilną i z różnymi postaciami ostrych zespołów wieńcowych (ACS), u których implantowano stent STENTYS®. Stent wszczepiono wszystkim pacjentom. W trakcie obserwacji krótkoterminowej 2 osoby zmarły zaraz po wykonaniu PCI — byli to chorzy z krytycznym zwężeniem pnia lewej tętnicy wieńcowej, we wstrząsie kardiogennym i zdyskwalifikowani z zabiegu pomostowania aortalno-wieńcowego. Ponadto u jednego z pozostałych pacjentów rozpoznano zawał serca typu 4b, a u dwóch chorych w trakcie implantacji wystąpiła dysekcja naczynia wymagająca założenia kolejnego stentu. Pomimo opisywanych powikłań u wszystkich chorych z badanej grupy stent został zaimplantowany w miejscu wybranym przez operatora. W trakcie długoterminowej obserwacji zanotowano konieczność ponownej rewaskularyzacji u 3 (7,8%) pacjentów w stentach STENTYS BMS. Nie wystąpiła restenoza w stentach STENTYS DES, nie zaobserwowano zakrzepicy w stentach DES/BMS.

Wnioski: Stent samorozprężalny STENTYS® umożliwia wykonywanie zabiegów angioplastyki u pacjentów ze złożoną morfologią zmian miażdżycowych. Charakteryzuje się niskim odsetkiem konieczności powtórnej rewaskularyzacji i dobrymi wynikami odległymi.

Słowa kluczowe: angioplastyka wieńcowa, ektazja naczyń wieńcowych, stent samorozprężalny

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