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First-in-man study of paclitaxel-eluting stent BiOSS (Bifurcation Optimisation Stent System) dedicated for coronary bifurcation stenoses: three months results

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Abstract

Background: The best treatment strategy for coronary bifurcation stenosis is still unknown. Dedicated bifurcation stents are the most promising solution.

Aim: To evaluate the safety and short-term efficacy of a new stent dedicated for coronary bifurcation stenosis.

Methods: A new bifurcation optimisation stent system (BiOSS, Balton, Poland) is made of 316L stainless steel and is coated with a mixture of biodegradable lactate polymer and paclitaxel (1 $\mu g/mm^2$). The stent consists of two parts, with different diameters according to Murray law connected by two 1.5 mm long bridges. BiOSS is mounted on a dedicated bifurcation balloon (Bottle, Balton, Poland) with markers of the proximal and the distal stent edge, and a third marker at the mid part showing the proximal end of its smaller distal part. The stent delivery is a rapid exchange system. Provisional T-stenting is the obligatory strategy. In order to optimise the result, Bottle balloon (nominal pressure: 10 atm) is inflated with mid marker positioned at the side branch ostium. Double antiplatelet therapy was planned for 12 months. Forty five patients with non-left main bifurcation stenosis (the n-LMB group), as well as 15 patients with left main (LM) bifurcation stenosis (the LMB group), were included in the prospective, feasibility and safety assessment registry. An intravascular ultrasound control is obligatory for all LM patients and strongly recommended for the remaining patients. Patients with ST-elevation myocardial infarction (STEMI) and Medina type 001 bifurcation lesions were excluded from the registry. The primary end-points of the study were: death, MI, in-stent thrombosis and target lesion revascularisation (in-hospital and one, three, six, and 12 months after the intervention). An angiographic control is planned at nine months in all patients. Here, we present the results of a three-month follow-up.

Results: The average age of the enrolled patients (63% males) was 67 ± 11 years. Thirty five (58%) patients had hypertension, and 16 (27%) were diabetic (five on insulin treatment). Almost half of the patients (29, 48%) had previous non-ST-elevation acute coronary syndrome treated with percutaneous coronary intervention. Six (10%) patients had previous coronary artery bypass grafting. In the LMB group (n = 15), there were: six with Medina type 111; five with type 010; three with type 110; and one with type 011 bifurcation lesions. In the n-LMB group (n = 45), the dominant vessel was left anterior descending (n = 26, 58%), followed by left circumflex (n = 15, 33%) and right coronary artery (n = 4, 9%). Medina type 111 lesions were present in 48% of patients. Intravascular ultrasound was performed in 37 (62%) cases. All BiOSS stents were implanted successfully (avg. pressure 12 atm), without any periprocedural complications. There were only seven (14%) cases with a second stent implanted within a side branch. There were four periprocedural increases of troponin interpreted as MI. At one month and at three months, all patients were uneventful (out-of hospital MACE rate 0%).

Conclusions: The BiOSS bifurcation dedicated stent is a feasible device, with promising safety and short-term clinical effectiveness/profile.

Key words: coronary stenting, bifurcation lesions, dedicated stents

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INTRODUCTION

Interventional treatment of coronary bifurcation lesions is still challenging for many cardiologists due to the relatively high risk of side branch (SB) closure and the long-term increased risk of restenosis [1–5]. The prevention of the SB compromise (composite of SB occlusion and occurrence of high grade flow-limiting ostial SB stenosis) after stent implantation and optimal stent scaffolding are the two main targets during the procedure.

It has been shown previously that with some stents it is possible to achieve a good scaffolding of the whole bifurcation, including the SB ostium, with a single stent after 'kissing balloon inflation' (KBI) [1–5]. This occurs when the SB is re-crossed with a wire through the most distal stent strut, situated at the tip of the bifurcation carina [2, 3, 5]. However, to do so, the operator has to go through the struts mesh with a wire to enter the SB exactly at the carina tip. This is frequently difficult to perform, especially by an inexperienced operator. To overcome these problems, different types of dedicated bifurcation stents have been proposed [6–13]. They could be classified as main vessel (MV) stents ensuring SB access, SB stents implanted before MV stenting, and dedicated for whole bifurcation region stents.

There are multiple problems with all currently available stents — generally most of the proposed systems are bulkier than a conventional stent and require a larger guide catheter. The majority of stents are introduced over two guidewires, which predisposes to wire crisscrossing and wire biasing (improper device orientation). The systems are more rigid and are difficult to advance to the target lesion in cases of significant proximal tortuosity. The aim of our study was to present the initial results of a new dedicated stent for coronary bifurcation lesions — the BiOSS Expert (Bifurcation Optimisation Stent System, Balton, Warsaw, Poland), the paclitaxel-coated drug-eluting stent (DES) version.

METHODS

Device description

The BiOSS project started at the end of 2007. After system development, a series of animal experiments were performed. On the basis of excellent experimental results, the ethics committee of the Central Hospital of the Internal Affairs and Administration Ministry permitted the start of human implantations (N 518 333 435).

The BiOSS Expert (Fig. 1) is a coronary bifurcation balloon expandable stent made of 316L stainless steel with a strut thickness of 120 μm and covered with a mixture of biodegradable polymer and an antiproliferative substance — paclitaxel. The profile of device pre-mounted on the balloon catheter is 1.08 mm. The stent strut/vessel area ratio varies between 15% and 18%. The smoothness of the surface is achieved by polishing using electromechanical methods. Nominal foreshortening of the stent is less than 0.5%. The BiOSS Expert has a unique delivery system, which assures exact stent placement at the point of the bifurcation. This system is a rapid exchange system compatible with 0.014" guide wires and 6 Fr (1.63 mm) guiding catheters. The lengths of the stents are 15 mm and 18 mm. The stent consists of two parts connected by two connection struts at the step-up middle zone. The proximal part of the stent has a larger diameter in relation to the distal part. The coating process of the stent by biodegradable polymer and paclitaxel uses the same technology as the Luc-Chopin2 stent, developed by the Balton Company (Warsaw, Poland). It enables the most flexible layer of biodegradable polymer as a paclitaxel carrier to be obtained [14]. The polymer layers release paclitaxel in a time-controlled process of their slow biodegradation (lasting about six weeks), inhibiting neointima formation process.

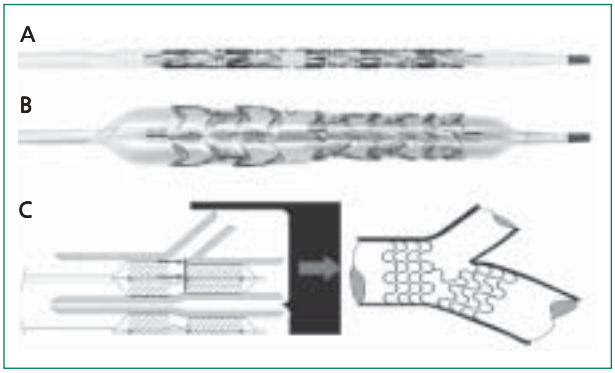

Figure 1. Bifurcation Optimisation Stent System (BiOSS). **A.** Basic view crimped on a balloon dedicated for bifurcation region optimisation (Bottle); **B.** Inflated system — the proximal and distal different diameter parts are clearly defined. The mid marker position shows exact placement of the beginning of the distal smaller diameter part. This marker must be positioned precisely against the carina tip; **C.** BiOSS principle of work — after balloon deflation, the stent conforms according to proximal and distal vessels diameters, as well as between-vessel angulations, permitting curve fitting according to main vessel angulation. This leads to good conformation against the side branch ostium

Angiographic analysis

Quantitative angiographic analyses were performed using commercially available software (Medis QCA version 5.0 and Dicom Works version 3.1.5b). Catheter calibration was used in all cases. Bifurcation lesions were classified according to the Medina classification, using an index of 1 for stenosis greater than 50% and 0 for no stenosis. The MV — the artery before SB delivery, the main branch (MB — artery beyond the ostium of SB), and the SB (the smaller vessel at the point of vessel divergence) were analysed separately.

The following parameters were calculated: reference vessel diameter (RVD) and minimal lumen diameters (MLD) be-

fore and after stenting; acute lumen gain at the proximal and distal limb of bifurcation (MLD at proximal or distal limb after stent implantation minus MLD in MV or MB); and the percent diameter stenosis (%DS) in the MV, MB, and SB before and after stent implantation. All reference diameters were measured 5 mm from the end of angiographically visible plaque in all three segments of bifurcation, without the use of interpolations (user defined reference diameters). Percent diameter stenosis (using parameters from each segment) was measured for each vessel segment separately using the following formula: %DS = [1 – (MLD/RVD)] × 100.

Study population

To evaluate the safety and feasibility of the paclitaxel-eluting BiOSS stents, 60 patients were enrolled into the multicentre registry comprising nine high volume (> 1,500 percutaneous coronary interventions per year) centres located in Poland.

Patients in the study represented almost all types of coronary bifurcation lesions (excluding Medina 001). They were included in the study if their serum creatinine level was below 2.0 mg/dL and if they were able and willing to take dual antiplatelet therapy for at least 12 months. Exclusion criteria included ST segment elevation myocardial infarction (STEMI), and lack of an informed consent.

Patients' characteristics represent a typical population encountered in this type of registry, with hypertension and dyslipidaemia as the commonest risk factors (58% and 40%, respectively). Almost half (48%) of the patients were classified as non-ST elevation myocardial infarction (NSTEMI) or unstable angina, and 27% were diabetics (Table 1). In the non left main bifurcation (n-LMB) group (n = 45), the dominant vessel was left anterior descending (LAD) artery (n = 26, 58%) followed by left circumflex (LCx) artery (n = 15, 33%) and right coronary (RCA) artery (n = 4, 9%).

The primary end-point was a major adverse cardiac event (MACE) which was defined as death, MI with or without ST-segment elevation, or the need for revascularisation of the target vessel. Secondary end-points included device performance and periprocedural safety.

To assess the effects of stent design on SB compromise, we made a comparison with a historical series of patients used for evaluation of factors for carina displacement [15]. We decided to use this population as a reference group. The same operators from some parts of participating centres in the current study were involved in these procedures; thus technical differences in interventions would be potentially eliminated. Moreover, the patient population has very similar characteristics to the present study group (Table 1).

Device success was calculated as a ratio of device implanted number to lesion number. Angiographic success was assessed as an end-procedure MB diameter stenosis of less than 20% and an SB ostial stenosis of less than 70%. The value for the SB angiographic end-point was chosen for two reasons. The first is based on previous fractional flow reserve data reports which showed that in this particular setting all ostial SB stenoses of less than 70% in diameter (and shorter than 5 mm) are functionally not significant [16].

Secondly, our own observations with magnetic resonance delayed gadolinium enhancement before and after bifurcation percutaneous coronary intervention, showed that the lack of necrosis at the area of SB of ostial stenosis after stenting is less than 73% [17].

The main points of the implantation protocol included: wiring of both branches, MV predilatation, SB predilatation according to operator decision, BiOSS implantation — balloon inflation at 10–12 atm for at least 20 s, stent postdilatation with Bottle balloon (Balton Co, Warsaw, Poland) at operator's discretion, SB postdilatation if SB ostial %DS > 70%. The final KBI was not required and was left to the operator's

Table 1. Patient population demographic characteristics

	Study group (n = 60)	Historical controls (n = 84)	P
Age [years]	67 ± 11	65 ± 11	NS
Sex — males	38 (63%)	56 (67%)	NS
Stable angina	31 (52%)	51 (60%)	0.048
Non-STEMI/unstable angina	29 (48%)	29 (35%)	0.048
STEMI		4 (5%)	
Hypertension	35 (58%)	64 (76%)	0.039
Elevated cholesterol/statin treatment	24 (40%)	69 (82%)	0.036
Diabetes	16 (27%)	28 (33%)	0.08
Smoking	6 (10%)	49 (58%)	0.001
Previous myocardial infarction	18 (30%)	26 (31%)	NS
Previous PCI	24 (38%)	28 (33%)	NS
Previous CABG	6 (10%)	7 (8%)	NS

STEMI — ST elevation myocardial infarction; PCI — percutaneous coronary intervention; CABG — coronary artery bypass grafting

decision. Intravascular ultrasound (IVUS) examination was mandatory for all LM cases.

Dual antiplatelet therapy (aspirin 75–300 mg plus clopidogrel 75 mg or ticlopidine 2 × 250 mg) was prescribed for 12 months. The patients were evaluated (history, physical examination, ECG) at 30 days and three months after the index procedure.

Statistical analysis

All values are presented as mean ± SD. An unpaired t-test or Mann-Whitney test was used as appropriate for comparisons, depending on the data distribution pattern. Type one error level was set at 0.05.

RESULTS

A total of 60 patients with 62 lesions were enrolled, and 62 BiOSS stents were successfully implanted at the sites of bifurcation lesions (100% device success rate).

The main procedural aspects are presented in Table 2. The MB was predilated in the majority of cases (almost 90%). Final KBI was rarely required, reflecting a good result in SB after the stenting. However, the SB was dilated in more than half of the patients, which is possible with a BiOSS stent, as its design permits independent deformation of proximal and distal parts and the correction of MV strut position is not necessary. We found that in order to achieve an optimal result in the SB ostium, as well as stent expansion in 30% of cases, an additional Bottle balloon was necessary. The Bottle balloon length was 10 mm, proximal/distal diameters 3.75/3.0 mm for all cases. However, the SB required additional balloon dilatation in more than half of the lesions.

Table 2. Procedural characteristics

Affected vessel — lesions	N (%)
MV predilatation	54 (87)
SB predilatation	19 (31)
Predilatation of both branches	15 (24)
MV stent diameter [mm]	3.62 ± 0.22
MB stent diameter [mm]	2.87 ± 0.22
Stent length [mm]	16 ± 1.44
Final kissing balloon inflation	13%
Bottle balloon postdilatation	27%
SB balloon postdilatation	53%
Additional stent in SB	6 pts (5 LM)
Additional stent in MV/MB	19 pts
Procedural time [min]	55 ± 13
Contrast volume [mL]	138 ± 39
Fluoroscopic time [min]	9.4 ± 3.4

MV — main vessel; MB — main branch; SB — side branch

With regard to the Medina classification: almost half (48%) of the patients represented lesions with morphology type 111; 18% had 011; 14% had 110; 12% had 010; 6% had 100; and 2% had 101. Thus, in our series, the percentage of true bifurcation lesions was 70% (Medina type xx1).

The angiographic data are presented in Tables 3–5. It is important to underline that the mean MV, MB and SB were well above 50% diameter stenosis. Neither in LMB nor in n-LMB was there a significant worsening of SB ostial stenosis after stent implantation. Final SB ostial diameter stenosis was at the 30%

Table 3. Angiographic data in the whole study group

Angiographic characteristics	Before stent	After stent	P
Main vessel:			
MV–RVD [mm]	3.48 ± 0.51	3.48 ± 0.36	NS
MV–%DS	49% ± 15%	3% ± 11%	< 0.001
Main branch:			
MB–RVD [mm]	2.88 ± 0.35	3.0 ± 0.23	NS
MB–%DS	67% ± 11%	9% ± 12%	< 0.001
MB lesion length [mm]	16 ± 3		
Side branch:			
SB–RVD [mm]	2.45 ± 0.45	2.47 ± 0.41	NS
SB–%DS	60% ± 21%	63% ± 16%	NS
SB–%DS — final [mm]		29% ± 17%	
SB lesion length [mm]	4.1 ± 1.46		
Angle alpha [degrees]	40 ± 15	39 ± 16	NS
Angle A [degrees]	58 ± 18	53 ± 17	0.04

All measures in millimetres unless noted otherwise; RVD — reference vessel diameter; MLD — minimal lumen diameter; %DS — percentage diameter stenosis; other abbreviations as in Table 2

Table 4. Left main group angiographic data

Angiographic characteristics	Before stent	After stent	P
Main vessel:			
MV–RVD [mm]	4.74 ± 0.62	4.82 ± 0.26	NS
MV–%DS	51% ± 15%	7% ± 9%	< 0.001
Main branch:			
MB–RVD [mm]	3.45 ± 0.17	3.37 ± 0.21	NS
MB–%DS	70% ± 12%	8% ± 10%	< 0.001
MB lesion length [mm]	14 ± 1		
Side branch:			
SB–RVD [mm]	2.85 ± 0.41	2.76 ± 0.21	NS
SB–%DS	61% ± 22%	61% ± 19%	NS
SB–%DS — final [mm]		20% ± 12%	
SB lesion length [mm]	4.3 ± 1.60		
Angle alpha [degrees]	46 ± 7	45 ± 9	NS
Angle A [degrees]	59 ± 17	55 ± 9	0.049

Table 5. Non-left main group angiographic data

Angiographic characteristics	Before stent	After stent	P
Main vessel:			
MV–RVD [mm]	3.41 ± 0.30	3.33 ± 0.16	NS
MV–%DS	49% ± 15%	3% ± 11%	< 0.001
Main branch:			
MB–RVD [mm]	2.92 ± 0.31	2.88 ± 0.28	NS
MB–%DS	66% ± 12%	9% ± 12%	< 0.001
MB lesion length [mm]	16 ± 3		
Side branch:			
SB–RVD [mm]	2.41 ± 0.42	2.39 ± 0.47	NS
SB–%DS	59% ± 21%	63% ± 16%	NS
SB–%DS — final [mm]		31% ± 19%	
SB lesion length [mm]	4.0 ± 1.45		
Angle alpha [degrees]	38 ± 12	35 ± 10	NS
Angle A [degrees]	54 ± 15	50 ± 11	0.04

range, which we assess as a very good result, taking into account the very low rate of additional SB stent implantation (16%).

Historical group comparisons

For the assessment of SB compromise effect of BiOSS stent, the patients from this study were compared to the historical cohort of 84 patients (92 bifurcation lesions), reported previously for examination of factors responsible for SB compromise [15]. This analysis revealed excellent results in the BiOSS group compared to the historical cohort — there was significantly less frequent SB compromise (Δ19% occurrence rate of stenosis > 70%), a trend towards less worsening of initial SB stenosis (Δ13%), and, most importantly, a statistically significant difference of Δ11% in occurrence of flow compromising stenosis appearance or branch closure (Fig. 2).

The angiographic success rate was 97%, because in two SBs it was not possible to achieve a final percentage diameter stenosis of less than 70% (in both cases the reason was ostial dissection with wire during SB recrossing). It is remarkable that in our group with 70% true bifurcation lesions and around 50% SB postdilatation after BiOSS implantation, more than 75% of lesions had a final diameter stenosis of less than 50% (Fig. 3). This figure is significantly higher than the historical control. More importantly, the frequency of high grade final SB stenosis was 3% in the BiOSS group, compared with 27% in the historical control, which is significantly different.

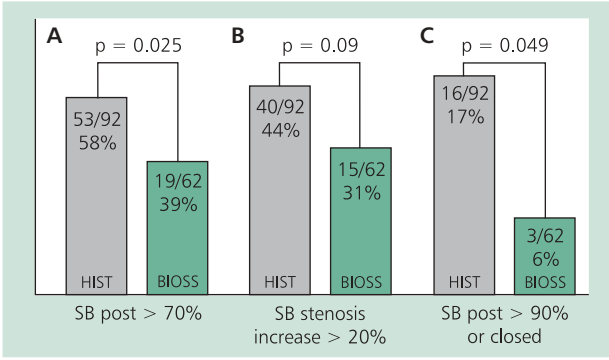

Figure 2. Angiographic comparison of immediate post stent implantation results in side branch (SB) ostium and historical controls. **A.** Difference in frequency of more than 70% SB %DS immediately after BiOSS implantation; **B.** Percentage of SB ostial stenosis worsening with more than 20%; **C.** Immediate post BiOSS occurrence of SB ostial flow-limiting stenosis occurrence; HIST — historical controls; BIOSS — the study group

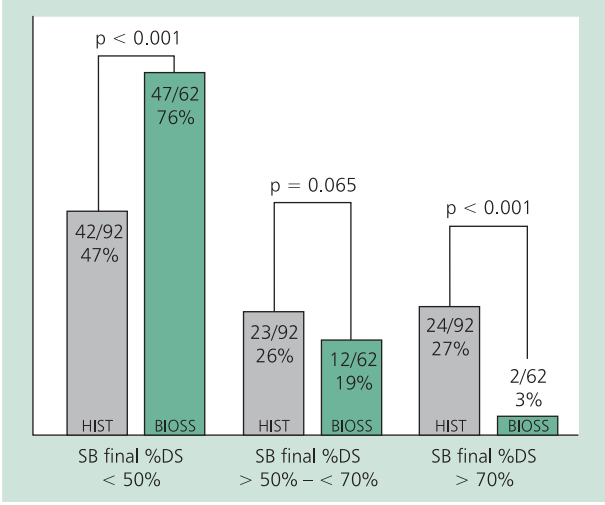

Figure 3. Distribution of final side branch (SB) diameter stenosis compared to results from historical controls. The differences in groups with final %DS less than 50% and more than 70% are statistically significant; HIST — historical controls; BiOSS — the study group

Follow-up results

Analysis of the 30 days (60 patients) and three months (45 patients) follow-up revealed excellent clinical results showing no death, target lesion (TLR), nor vessel (TVR) revascularisation. There were four cases of in-hospital increase of troponin and CK-MB levels qualified as non-Q MI, giving a procedural success rate of 93%. No further incidents of MI were observed up to three months of follow-up. The analysis of the remaining data (QCA and IVUS) is pending.

DISCUSSION

Even after the introduction of DES in the treatment of coronary bifurcation lesions, important basic problems remain [18]. These problems include periprocedural SB occlusion or severe stenosis, high rate of in-stent restenosis, and increased propensity for stent thrombosis [1, 2, 6, 19, 20].

It has been suggested that these problems are related to non-dedicated design of the conventional stent intended for treatment of straight vessel segments. Thus, any deformation of the stents during bifurcation implantation depends on the stent cell shape, size and material properties [18]. To resolve these problems, it has been suggested that dedicated bifurcation stents should be developed [1, 2, 18]. However, this particular 'dedication' remains undefined and unclear — the stent could be dedicated for a patient fitting the anatomical characteristics of a particular bifurcation point (vessel diameters, angulations), giving better haemodynamic conditions; or the stent could be dedicated for the operator to make the procedure quicker and safer, eliminating or limiting SB compromise. Probably the best option is the combination of both characteristics.

Currently available stents generally target the second requirement. Three groups of stents are available now — proximal MV stent (Axxess, Devax, USA), MV stenting across the SB with different designs making possible permanent access to the SB, and finally purely SB dedicated stents (Tryton, Sideguard, Biguard). None of these stents match proximal — distal MV size difference, nor take into account the between--vessel angulations. The device success rate varies considerably (75–100%); however, the study with 100% success was performed in only 11 patients. For all other devices, the success rate is around 85%. The proximal MV stent and SB only stents require additional stent implantation for non-intended vessel. Stents designed to have permanent access to SB are implanted over two wires, which in reality makes the procedure more difficult and demanding rather than simplifying it (which was the primary intention of those stents). The reasons for this are wires crisscrossing, wire-bias in proper orientation of device to SB (rotational and axial positioning). This, along with the requirement for a larger guide catheter explains why dedicated stents have not become popular in the interventional cardiology community.

The BiOSS stent is completely different from the above systems. The stent is designed to be user friendly: it is tracked over one wire and its profile is quite low (1.08 mm), which makes it possible to implant it even through a 5 Fr guiding catheter. The stent fits the bifurcation anatomy — it matches the proximal — distal diameters of the MV; as it permits deformation in its midpart, it can adapt exactly to the MV–MB angle, making a wide opening to the SB. If the SB must be dilated, stent recrossing is very easy, because wider proximal and narrow distal parts give step-down at carina tip region, in this way self directing the wire to the SB. The proximal and distal parts of the stent work independently, and the SB can be safely dilated without the need for KBI as there is no deformation of the contralateral wall strut. This simplifies and shortens the procedure.

The immediate and short-term results of BiOSS implementation are excellent. The device has been 100% success-

fully implanted without significant difficulties, even in cases with direct stenting. If it was necessary, the stent was post dilated with a dedicated Bottle balloon, which is actually the same as used in the stent delivery system, but of a shorter length. The longer (more than 20 s) inflation was mandatory to achieve complete stent apposition without damage at the stent ending. There were two cases with transient SB closure during wire recrossing, probably induced by wire manipulation. The periprocedural rate of increase in cardiac enzymes levels was quite low.

Limitations of the study

The major limitations of our study are the small sample size and the short duration of follow-up. However, the first results are very promising with actual 0% MACE rate out of hospital. It could be argued that the existence of some incompletely covered region in the carina region could predispose to restenosis. However, the stent in reality performs remarkably well, without plaque prolapse observation in this region. Moreover, the higher relative drug concentration in the proximal stent part (because of its larger size), and possible distal drug diffusion, could prevent restenosis occurrence, although this remains merely an hypothesis.

CONCLUSIONS

Simple and fast bifurcation treatment with a single dedicated bifurcation stent (BiOSS) is feasible and highly successful (100% implantation rate). The BiOSS stent reduces SB compromise in comparison with an historical control. The short term clinical results are very promising, and long-term observations are pending.

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Conflict of interest: *none declared*

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Rejestr stentu uwalniającego paklitaksel dedykowanego zwężonym bifurkacjom wieńcowym (BiOSS): wyniki 3-miesięczne

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Streszczenie

Wstęp: Optymalne leczenie zwężeń bifurkacyjnych nie jest obecnie jednoznacznie ustalone. Stenty przeznaczone specjalnie (tzw. dedykowane) do leczenia bifurkacji wieńcowych wydają się najbardziej obiecującym rozwiązaniem.

Metody: We współpracy z firmą Balton (Warszawa, Polska) stworzono stent dedykowany zwężeniom bifurkacyjnym — BiOSS (stent optymalizujący bifurkację). Stent ten jest wykonany ze stali medycznej (316L) i pokryty mieszaniną biodegradowalnego polimeru mleczanowego i paklitakselu (1 $\mu g/mm^2$). Stent składa sie z 2 części o różnych średnicach, wyznaczonych zgodnie z regułą Murraya i połączonych ze sobą dwoma mostkami o długości 1,5 mm. Stent BiOSS jest zamontowany na specjalnym baloniku w kształcie butelki (Bottle, Balton, Polska) ze znacznikami proksymalnego i dystalnego końca stentu. Ponadto na baloniku doprowadzającym umieszczony jest trzeci znacznik, tzw. środkowy, wskazujący proksymalny koniec dalszej części stentu. System dostarczający stent zalicza się do typu tzw. szybkiej wymiany (*monorail system*). Przyjętą strategią leczenia bifurkacji w ramach Rejestru była obligatoryjna implantacja stentu w naczyniu głównym z ograniczeniem do niezbędnej implantacji stentu w naczyniu bocznym (*provisional T-stenting*). W celu optymalizacji wyniku implantacji stentu BiOSS zalecano użycie balonika Bottle, który był poddawany inflacji (ciśnienie nominalne: 10 atm) w pozycji, w której jego środkowy marker znajdował się na wysokości ujścia gałęzi bocznej. Podwójną terapię przeciwpłytkową zaplanowano na 12 miesięcy. Do prospektywnego Rejestru oceniającego kliniczną przydatność i bezpieczeństwo użycia stentu BiOSS włączono 45 chorych ze zwężonymi bifurkacjami z wyłączeniem pnia głównego lewej tętnicy wieńcowej (grupa n-LMB) oraz 15 z istotnymi zwężeniami pnia głównego lewej tętnicy wieńcowej (grupa LMB) zostało włączonych. Badanie metodą ultrasonografii wewnątrzwieńcowej (IVUS) wykonywano obligatoryjnie u chorych z grupy LMB i zalecano w pozostałych przypadkach. Pacjenci z zawałem serca z uniesieniem odcinka ST i osoby ze zwężeniami typu 001 wg klasyfikacji Mediny nie byli włączani do Rejestru. Pierwotne punkty końcowe badania obejmowały: zgon, zawał serca, zakrzepicę wewnątrzstentową i rewaskularyzację zwężenia leczonego pierwotnie (wewnątrzszpitalne oraz 1, 3, 6 i 12 miesięcy po implantacji stentu BiOSS). Kontrolę angiograficzną zaplanowano u wszystkich chorych po 9 miesiącach od pierwotnego zabiegu.

Wyniki: Średnia wieku pacjentów włączonych do Rejestru (63% mężczyzn) wyniosła 67 ± 11 lat; 35 (58%) osób miało nadciśnienie tętnicze, a 16 (27%) cukrzycę (5 stosowało insulinoterapię). Prawie połowa chorych (29; 48%) przebyła ostry zespół wieńcowy bez przetrwałego uniesienia odcinka ST leczony angioplastyką wieńcową, a 6 (10%) osób — operację pomostowania aortalno-wieńcowego. W grupie LMB (n = 15) było: 6 chorych ze zwężeniem typu 111, 5 — 010, 3 — 110 i 1 — 011 wg klasyfikacji Mediny. W grupie n-LMB (n = 45) naczyniem głównym była gałąź przednia zstępująca (n = 26, 58%) i kolejno: gałąź okalająca lewa (n = 15, 33%) i prawa tętnica wieńcowa (n = 4, 9%). Zwężenie typu 111 wg klasyfikacji Mediny było obecne w 48% przypadków. Badanie IVUS wykonano u 37 (62%) chorych. Wszystkie stenty BiOSS zostały z powodzeniem implantowane (średnie ciśnienie: 12 atm) bez jakichkolwiek okołozabiegowych powikłań. Stent w naczyniu bocznym implantowano jedynie u 7 (14%) pacjentów. U 4 chorych wystąpił okołozabiegowy wzrost stężenia troponiny spełniający kryteria zawału serca. W okresie 3-miesięcznej obserwacji u chorych nie wystąpiły niepożądane zdarzenia sercowo-naczyniowe.

Wnioski: Dedykowany bifurkacjom wieńcowym stent BiOSS jest przydatnym klinicznie stentem z obiecującym profilem bezpieczeństwa i średnioterminowej skuteczności.

Słowa kluczowe: bifurkacje wieńcowe, stent dedykowany, przezskórna interwencja wieńcowa

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