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The fate of small side branches following drug eluting stent implantation

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ABSTRACT

Objectives: Although drug eluting stents (DES) have documented convenience in bifurcation lesions, possible unfavorable effects on small side branch ostium (SBO) remain a question. We aimed to explore the effects of DES on small jailed SBs (1.5–2.25 mm) which originated from the lesion on the main vessel and were not treated with either stenting or balloon dilatation.
Methods: Angiographic data of 107 consecutive patients (129 SB) with Medina 1,1,1 or 1,1,0 lesions were evaluated at the time of procedure and at the follow-up.
Results: Of all DES used, 70 (54.7%) was sirolimus-eluting, 39 (30.5%) was paclitaxel-eluting and 20 (14.8%) was zotarolimus-eluting. The diameter of SBs was 1.84 ± 0.41 mm with a stenosis of $20.7 \pm 26.6\%$ at SBO at baseline. The lesion at the SBO had progressed after the procedure when the pre vs postprocedure values and follow-up vs pre-procedure values are compared ($20.7 \pm 26.6\%$ vs $29.4 \pm 27.4\%$; $p < 0.0001$ and 25.4 ± 25.1 vs $20.7 \pm 26.6\%$; $p = 0.004$ respectively). A significant reduction in stenosis was revealed over the follow-up (29.4 ± 27.4 vs 25.4 ± 25.1 respectively; $p = 0.013$). The severity of the disease at the SBO at baseline was the only parameter that affected the severity of SB stenosis in acute, longterm and follow-up. Additional parameters with influence on SB patency at different times were female gender, stent deployment with low pressure, cTFC of the main lesion, age, cTFC of the lesion, late loss index and the preprocedure TIMI flow grade of the SB.
Conclusions: Although there was a significant deterioration of SBO immediately after stenting, follow-up data showed that the lesion at SBO improved but remained worse than baseline.
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1. Introduction

Coronary bifurcation sites which are under pronounced endothelial shear stress, are particularly prone to atherosclerotic process [1]. Bifurcation lesions represent one fifth of all coronary interventions with higher complication and lower long term patency rates in which, both long term restenosis and acute occlusion/narrowing pose major problems for the treatment [2]. Current approach is treating the main branch (MB) with a stent and provisional stenting of the clinically significant side branch (SB) [2,3]. Consequently, some of the smaller side branches are left untreated to their fate on operator's judgment or due to technical challenges. With bare metal stents, the SBs at the level of main lesion were frequently sacrificed. After introduction of drug eluting stents (DES), positive data have been accumulated on the stent behavior and low rates of restenosis, making DES as the stent of choice in most patients [2]. Yet, skepticism on the possible unfavorable effects of antiproliferative and anti-inflammatory properties of DES on endothelization of small SB with the risk of early or late thrombosis remains as a question.

Herein this study, we aimed to explore the immediate and long term (6 months) effects of DES on small jailed SBs (1.5–2.25 mm) which originate at the level of the lesion on the MB and do not receive any intervention.

2. Methods

In the study, a 'bifurcation lesion' represented a coronary lesion which resulted in narrowing of MB at the level where a SB originates, while the side branch ostium (SBO) may or may not be diseased. This definition included Medina 1,1,0 and 1,1,1 lesions. Only the small side branches with a diameter of 1.5 mm to 2.25 mm originating at the level of lesion and were not treated with dilatation or stenting are analyzed.

After approval from local Ethics Committee, 107 consecutive patients with stable coronary artery disease and bifurcation lesions in

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which a DES (Sirolimus eluting stent (SES), paclitaxel eluting stent (PES) or Zotarolimus eluting stent (ZES)) was implanted were involved to the study. All patients had control coronary angiography and they gave informed consent before inclusion. The study protocol complied with the Declaration of Helsinki.

Medical and angiographic records of 87 male and 20 female patients with a total of 129 SBs were evaluated. The traditional risk factors of the patients recorded were gender, age, the presence of diabetes mellitus, hypertension, family history of coronary artery disease, hyperlipidemia and smoking. Age was categorized in three categories as <50, 50–65, >65 years. The lesions were located on branching points of left anterior descending artery (LAD), circumflex artery (Cx), right coronary artery (RCA) and 'protected' left main coronary artery (LMCA).

3. Angiographic data

Both of the lesion on the MB and lesion on the SB, if any, were evaluated quantitatively during coronary angiography. All quantitative angiographic measurements were derived from QCA-Telemedicine Technologies, MEDCON software. The measurements were made in diastole after calibration with the guiding catheter. The angiographic data were analyzed before the procedure, immediately after the procedure and at the follow-up coronary angiogram. At the time of follow-up CAG, segment within 5 mm proximal and distal ends of the stent were evaluated.

Among the angiographic parameters evaluated were lesion length, reference diameter of MB, percent stenosis on the MB, lesion type classified by ACC/AHA [4], TIMI flow grade [5], corrected TIMI frame count (cTFC) [6] of the MB and SB. Corrected TIMI frame count (cTCT), which is an index of coronary perfusion, is considered as a predictor of restenosis. It involves the frame count of contrast agent from the ostia to the standardized segments of coronary arteries. For LAD, which is longer when compared to other coronaries, this number is corrected by dividing the calculated number by 1.7 [6]. In the study, cTFC is calculated for both main and side branches. The cTFC of the side branches were calculated as the number of frames elapsed from the ostia to the end of the evaluated side branch. Whether a predilatation of the MB was employed or the maximal pressure achieved during stent deployment were also recorded. A pressure higher than 14 atmospheres was designated as high pressure inflation. Late loss index (late loss/acute gain) represents the percent loss of lumen diameter which was gained immediately after the procedure and was also evaluated to reveal the influence of restenosis on SBO. The SB involved was not treated with a stent or balloon due to small vessel size or difficult rewiring.

The difference between the severity of stenosis of SBO before and immediately after the procedure reflects the acute effect of the procedure and is designated as '*acute effect*' in the text and tables. The difference between the pre-procedure stenosis and stenosis of SB at the follow-up angiogram, on the other hand, represents the *long term effect* of the procedure and is entitled accordingly. Atherosclerosis is a progressive disease and the *course of the disease* at the SBO during follow-up is also evaluated by comparing the percent stenosis difference between the immediately post-procedure and follow-up angiogram of the side branches. For the purpose of the study this is designated as '*disease course*'.

4. Statistical analysis

Both mean ± standard deviation and median (minimum–maximum) values are used in the descriptive statistics of the data. The distribution of the variables is tested by Kolmogorov–Simirnov test. The quantitative data are analyzed by Mann–Whitney U test. Repetitive measurements were analyzed by Wilcoxon test and Mc Nemar test. The correlation of the variables is evaluated by Spearman correlation analysis. All data is analyzed by SPSS 22.0 Software.

5. Results

A total of 107 patients, 20(18.7%) female and 87(81.3%) male with a mean age of 60.9 ± 10.1 years, are involved into the study. A follow-up CAG was carried out within 7.44 ± 3.1 months of index procedure. Of all DES used, 70 (54.7%) was SES, 39 (30.5%) was PES and 20 (14.8%) was ZES.

The demographic and angiographic characteristics of the study population are presented in Table 1. Based on the demographic characteristics, one third of the patients were diabetic with relatively high risk criteria. Similarly, one third of the lesions possessed angiographically high risk characteristics (ACC AHA classification B2 and C). In half of the patients, predilatation with 13.76 ± 1.5 atmosphere was employed. The diameter of SBs was 1.84 ± 0.41 mm with a stenosis of 20.7 ± 26.6% at the SBO.

When all the SBs are evaluated, 5 SBs (4%) were acutely lost after the procedure, while the follow-up CAG revealed that 3 out of 5 acutely occluded SBs were recanalized. Only 1 SB was seen to be occluded on the follow-up angiogram after good immediate result (0.008%).

A more detailed evaluation of outcome of MB stenting on SBO is summarized in Tables 2, 3 and Fig. 1. The lesion at the SBO had progressed severely after the procedure when the pre and post-procedural values for lesion at SBO are compared (21 ± 27.3 vs 29.4 ± 27.4 respectively; $p < 0.0001$). Similarly, there was a significant increase in stenosis when the follow-up and pre-procedure values were compared (25.4 ± 25.1 vs 21.5 ± 27.3 respectively; $p = 0.004$). Interestingly, when we compared the post-procedure and follow-up stenosis rates, a significant reduction in stenosis was revealed over the follow-up (29.4 ± 27.4 vs 25.4 ± 25.1 respectively; $p = 0.013$) (Table 2). Table 3 shows the acute effect of the procedure on the distribution of stenosis rates at SBO. There was a significant increase in the

Table 1
Demographic and angiographic characteristics of study population.

		Number	Percent (%)	Mean ± SD
Demographic data				
Female		20	18.7	
Age, yrs				60.9 ± 10.0
Hypertension		101	78.3	
Hyperchlosterolemia		91	70.5	
Diabetes mellitus		48	37.2	
Smoking		41	31.8	
Family history		30	23.3	
Angiographic data				
Main vessel	LAD	76	58.9	
	Cx	17	13.2	
	RCA	30	23.2	
	Obtus	3	2.3	
	Saphenous	1	0.8	
	LMCA	2	1.6	
Reference diameter, mm				2.84 ± 0.39
Stent diameter, mm				2.89 ± 0.34
Lesion length, mm				13.53 ± 7.5
Lesion stenosis,%				73.39 ± 13.3
Stent length, mm				20.38 ± 7.4
Lesion type	A	44	34.1	
	B1	40	31.0	
	B2	21	16.3	
	C	24	18.6	
Predilatation		73	56.6	
Maximum pressure, atm				13.8 ± 1.5
Diameter of side branch, mm				1.84 ± 0.41
Lesion at side branch ostium, %				20.7 ± 26.6
TIMI flow of side branch				2.63 ± 0.7
Open stent design		25	19.4	
Drug type	SES	70	54.3	
	PES	39	30.2	
	ZES	20	15.6	

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